Supreme Court, U.S.
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No._____

In The
Supreme Court of the United States

LISA ANN PAFFORD and RICHARD LEON PAFFORD, PARENTS AND NEXT FRIENDS OF RICHELLE LORRAE PAFFORD, a minor,

Petitioners,

-vs.-

MICHAEL O. LEAVITT, SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,

Respondent.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

PETITION FOR WRIT OF CERTIORARI

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QUESTIONS PRESENTED

1. Are special masters, appointed under the Vaccine Act by the Court of Federal Claims and vested with its trial jurisdiction, "inferior officers" whose appointment is proper under the Appointments Clause of the United States Constitution?

2. What is the constitutional threshold of maximum judicial deference that may be afforded to the adjudications of the Office of Special Masters, an "inquisitorial" Article I tribunal?

LIST OF PARTIES

All parties to this and related litigation in the tribunals below whose judgment is sought to be reviewed are listed on the caption of the case.

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OPINIONS BELOW

The affirming panel opinion and judgment of the Court of Appeals of the Federal Circuit (reported at *Pafford v. Secretary of DHHS,* 451 F.3d 1352 (Fed. Cir. 2006), Appendix C, *infra* App. 57-App. 78) is dated the 20th day of June, 2006, rehearing denied, October 24, 2006 (Order, Appendix D, App. 79-App. 80). The opinion of the United States Court of Federal Claims, *Pafford v. Secretary of DHHS,* 64 Fed.Cl. 19 (2005), (Appendix B, *infra* App. 24-App. 56) was entered on January 25, 2005. The master's Entitlement Decision (reported as *Pafford v. Secretary of DHHS,* 2004 WL 1717359 (Fed.Cl.Spec.Mstr.), Appendix A, *infra* App. 1-App. 23) was entered July 16, 2004 .

JURISDICTION

The judgment of the court of appeals was entered on June 20, 2006, rehearing and rehearing *en banc* denied, October 24, 2006. Petitioners invoke the jurisdiction of this court under 28 U.S.C. § 1254 (1).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

This matter presents a constitutional challenge to the current, amended National Childhood Vaccine Injury Compensation Act of 1986, 42 U.S.C. §§ 300aa-10 *et seq.*[1], particularly, the "technical" amendment of 1989 to § 300aa-12, defining and allocating trial jurisdiction. The applicable constitutional provisions (App. 81) are found in Article II, section 2, clause 2, the "Appointments Clause." Also challenged is the standard of review enacted in 1989 and

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1. The provisions of the Vaccine Act are referred-to hereinafter in this petition simply by section or subsection number. For example, the pivotal standard of review subsection from 42 U.S.C. § 300aa-12 will be cited simply as "§ 300aa-12 (e) (2) (B)."

found at § 300aa-12 (e) (2), which creates the Appointments Clause problem and, as applied, violates the Due Process clause of the Fifth Amendment. (App. 81.) Provisions of the Vaccine Act pertinent to this matter are also set forth and reproduced in Appendix E, *infra* App. 81-App. 88.

STATEMENT

On March 24, 1998, Richelle Lorraine Pafford was injected with multiple childhood vaccines—antigens from Diphtheria, Whooping Cough, Measles, Mumps, Rubella, Tetanus and Polio—at the Cheyenne, Wyoming office of her pediatrician. By April 30, 1998, Richie had developed a permanent, systemic, autoimmune, inflammatory condition diagnosed as "Still's Disease." The disorder is known to modern American medicine as systemic-onset Juvenile Rheumatoid Arthritis ("JRA" or "soJRA"). App. 7, *infra*.

A timely petition was filed under the National Childhood Vaccine Injury Compensation Act in the United States Court of Federal Claims. The matter was assigned to Special Master Richard Abell, and over the ensuing months, the petitioners perfected the showing-by-affidavit contemplated by § 300aa-11. (App. 83.) The showing was formulated to satisfy the legal causation-in-fact "test" articulated by Chief Special Master Golkiewicz in the published opinion styled as *Stevens v. Secretary of DHHS,* ("Ruling on Petitioner's Motion for Summary Judgment"), 2001 WL 387418 (Fed.Cl.Spec.Mstr.)[2].

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2. *Stevens*—a seminal opinion which has been criticized and partially repudiated, marked the Chief Special Master's effort to articulate a workable test for actual causation cases. It contemplated five "prongs" of causation evidence: 1) the proof of medical plausibility of the injury, 2) proof of confirmation of the medical plausibility from the medical community and literature, 3) proof of an injury recognized by the medical plausibility evidence and literature, 4) proof of a medically acceptable temporal relationship between the vaccination and the onset of the injury, and 5) proof of the elimination of other causes. The instant case hinged on

(continued...)

The government's pleading in the matter—its "Rule 4 Report," contemplated by Vaccine Rule 4(b), Appendix B, RCFC—was accompanied by and incorporated expert submissions. Significantly, no alternative causation by "factors unrelated to the administration of vaccines" was pleaded, as contemplated by § 300aa-13 (a) (1) (App. 86-App. 87), even though Richelle had displayed some minor illnesses prior to vaccination. The government's pleaded position was only to challenge the sufficiency of petitioners' showing. The government characterized the petitioners' theory as "simple reliance on temporal association and the inability to identify another cause."

The record was developed with written reports from two petitioners' experts, and from three experts hired by the government. Dozens of medical articles were filed. Two briefs addressing the theory of causation were filed by the petitioner. The master finally scheduled an "expert only" hearing, in Washington, D.C., on the 7th and 8th of July, 2000, where the medical records were regarded as a factual stipulation. The government's prehearing brief characterized the petitioners' theory as being based on ***"proximal temporal association alone."*** Emphasis added. The government's experts acknowledged that the time frame was medically appropriate[3].

At hearing, the debate concerned the mechanism of injury, and the question of whether petitioners' could sufficiently prove "specific causation" in Richelle Pafford's

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the fourth prong, the "time frame" issue.

3. One government expert, Dr. Moulton, called the time progression from shots to disease in Richelle Pafford's case a "***necessary*** chronology" (emphasis in the original) for an inference of causation, but not "sufficient." Another government expert, Dr. Berger, referred to the temporal association between the shot and the disease as the petitioners' only "direct evidence" of causation.

case. The master entertained closing argument briefs[4] after the trial was over. The record proved that JRA is an autoimmune mediated inflammatory disease. Petitioners' expert Dr. Levin explained this mechanism down to the cellular level, describing the inflammatory agents (cytokines) that the vaccines and the disease have in common. (Decision, App. 12-App. 13.) The government's expert Dr. Rosé confirmed these details. (*Ibid.*) The petitioners' two experts testified that the temporal relationship between the vaccine administration and the onset of disease was what one would medically expect. Medical literature was used to illustrate the expected time-frame of the causation theory.

Thus, when the statutory "decision" issued under § 300aa-12 (d) (3), the petitioners were effectively ambushed. The master *sua sponte* raised an unpleaded "time frame" element, and ruled that it would be dispositive. At 2004 WL 1717359 p. *7 (App. 19, *infra*), the master stated, "Petitioners provide no objective evidence indicating an appropriate time frame in which Still's disease will manifest subsequent to a triggering event." The master decreed that the petition must be rejected, stating, "The link missing from Petitioners' argument that gave this Court pause was the lack of any defined time period[5] in which one would expect to see the onset of Still's disease subsequent to a triggering event." (Decision, App. 22, *infra.*)

The master had not failed to exercise his

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4. The master did not invite argument on the pivotal "time-frame" theory in ordering final summation briefs, nor otherwise apprise petitioners that the issue was under "inquisitorial" consideration.

5. The Decision acknowledges that the "objective evidence" the master would demand from petitioners apparently does not exist, stating, "it appears, at least to this Court, that the timing of onset of Still's disease subsequent to a triggering event is not a telling characteristic of the disease." (App. 19, *infra.*)

"inquisitorial" powers[6]. But no such "inquisitory" exercise was attempted with regard to the "defined time period" problem, and the master recommended dismissal. The Petitioners' only recourse under the Act was a Motion for Review under § 300aa-12 (e). The Motion for Review raised legal error under the statute, identified as a denial of Due Process, in the master's determination of the issue without seeking input from the parties—especially when the special master otherwise invoked his "inquisitorial" role.

The Court of Federal Claims[7] rejected the Due Process argument, and ruled that anticipating the time frame issue would be part and parcel of "the traditional tasks" of the parties, *i.e.*, "identifying and developing information supporting or opposing an award, securing and presenting fact witnesses and expert testimony, and meeting their respective burdens of proof[8]." *Pafford,* 64 Fed.Cl. at 33 (App. 49, *infra*) citing Guidelines for Practice Under the National Vaccine Injury Compensation Program, § V. Judge Block went on, stating, "the role of a medically accepted temporal relationship between a vaccination and the onset of a

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6. The master quoted the Federal Circuit (Decision, fn 33, App. 14, *infra*) in stating, "The Special Master is not required to be a 'potted plant." The citation (*ibid.*) refers to legislative history and "an 'inquisitorial' format, with the [special] master conducting discovery (as needed), cross-examination (as needed) and investigation.'" The footnote concludes, "Accordingly, the Court, *sua sponte*, researched Dr. Levin's theory and found additional support for his assertions regarding the autoimmune mediated nature of rheumatoid arthritis."

7. The limited and deferential Vaccine Act review is more fully described in the Vaccine Rules, RCFC Appendix B, part V ("Review of a Special Master's Decision") Rules 23 to 28.

8. Judge Block expanded beyond the master's Decision in articulating the petitioners' burden to make a *prima facie* showing, citing *dicta* from *Munn v. Secretary of DHHS,* 970 F.2d 863 (Fed.Cir.1992) and stating that "an actual-causation vaccine petitioner 'must prove by a preponderance of the evidence that the vaccine, and ***not*** some other agent, was the actual cause of the injury.'" (App.43, *infra*, emphasis supplied in the original.)

subsequent condition has long been recognized as an important, if not essential element of a petitioner's burden of proof in Vaccine Program cases." *Ibid.*

Still seeking a day in court to address—and easily dispose of—the "time frame" issue, petitioners filed a "Rule 59 Motion for Reconsideration; Renewed Request [9] for Oral Argument," specifically requesting the right to present evidence. The motion was denied on March 8, 2005, as an effort to "reargue," without mention of the request for an additional hearing

The petitioners then filed a statutory appeal to the Federal Circuit, under § 300aa-12 (f). The Federal Circuit's panel majority would also reject the Due Process challenge, stating that "the petitioner knew of the medically accepted time frame issue well before the end of the trial." *Pafford,* 451 F.3d at 1359[10], App. 67. The panel majority believed—contrary to the record—that petitioners' entire case for the "proximate temporal relationship" element [11] of causation hinged upon a single expert whose qualifications

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9. A request for oral argument had been granted when the matter was on review by the the Hon. Diane Gilbert Sypolt in Court of Federal Claims, but that date was lost when the matter was reassigned to Judge Block. The shuffling even caused Judge Block's decision to be untimely, past the 120-day limit found in § 300aa-12 (e) (2). (At App. 26 the Court will find the filing date, August 16 of 2004. Affording 30 days for the Respondent's brief, the 120-day limit of jurisdiction under § 300aa-12 (e) (2) expired before the January 25, 2005 opinion date set forth at App. 24.)

10. The panel decision evoked a strong dissent from Circuit Judge Dyk (App. 67-App. 77, *infra*), who perceived the creation of a new element of proof, and repudiation of the two newest Federal Circuit "actual causation" cases, *Capizzano v. Secretary of DHHS*, 440 F.3d 1317 (Fed.Cir.2006) and *Althen v. Secretary of DHHS*, 418 F.3d 1274 (Fed.Cir.2005).

11. In *Althen*, announced after the master's decision issued, the Federal Circuit established a three-element test for actual causation, to-wit: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Capizzano*, 440 F.3d at 1324.

were denigrated by the master. *Ibid.*

Petitioners moved for panel rehearing, pointing out overlooked references in the record, from both parties, to the appropriateness of the time-frame. Petitioners also sought rehearing *en banc*, by virtue of unresolved conflict between *Pafford, Althen,* and *Capizzano.* Rehearing was denied. (App. 79-80.)

REASONS FOR GRANTING CERTIORARI

The Vaccine Act creates a structurally unconstitutional Article I tribunal. A "technical amendment" in 1989 removed the trial jurisdiction from the Court of Federal Claims, and granted it to the subordinate Office of the Special Masters. The amendment also replaced *de novo* review with "deferential" review. Congress thereby elevated special masters to a position of ultimate authority, in violation of the Appointments Clause.

This defect "goes to the validity of the . . . proceeding that is the basis for this litigation." *Freytag v. C.I.R.*, 501 U.S. 868, 879 (1991)[12]. So deferentially are these masters reviewed, that the historic court to whom such masters are supposedly an "adjunct" is said to be without original jurisdiction, and imbued with **only** a "review" jurisdiction. Indeed, the Act—after the unconstitutional, "technical" amendment—states that "the United States Court of Federal Claims shall have jurisdiction to undertake a review ***of the record*** of the proceedings . . ." App. 85, *infra*, emphasis added[13].

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12. Even in Justice Scalia's *Freytag* opinion, concurring in the result but questioning the grant of *certiorari* (*id.*, 501 U.S. at 898), one finds support for reviewing a "defect of authority" that "relates to basic constitutional protections designed in part for the benefit of litigants."

13. On the basis of this language from § 300aa-12 (e) the Federal Circuit ruled in an earlier decision that the Vaccine Act strips the Court of Federal

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Moreover, the fundamental statutory feature of vaccine cases, despite their adversarial nature, is the "inquisitorial" role of the master. The system abjures the Federal Rules. And in the absence of rules, compounded by the lack of binding precedents, the Congressional experiment in an inquisitorial system has resulted in a tribunal overtly partial to the government at every legal and procedural juncture. The master literally **pleaded** the defenses in this matter, after the trial—and briefing—was finished. And the legal standard is *ad hoc*; at no time in the years before the Decision did the master even specifically disclose the legal standard upon which the tribunal would decide the case.

The Office of Special Masters as created by the 1989 technical amendments is in contemplation of the Constitution a subordinate body within an executive agency (*i.e.*, the Court of Federal Claims is a "legislative court"). And while under *Freytag, supra* at 889, the Court of Federal Claims may be regarded as a "judicial" body for purposes of the Appointments Clause [14], the "trial" jurisdiction is exercised only by the subordinate office, wielded by supposedly "inferior officers." But nothing is "inferior" about the masters' judicial role. Not even the Chief Special Master is required to supervise or maintain consistency of doctrine. Any master's Decision, absent appeal, is regarded as a "final determination" under subsections 300aa-12 (e) (3) and (f). (App. 86.)

Moreover, "deferential" review tolerates outright

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Claims of "plenary" and New Trial jurisdiction. *Turner v. Secretary of DHHS*, 268 F.3d 1334, 1339 -1340 (Fed. Cir. 2001)(Court of Federal Claims could not "conduct a new trial to review the evidence *de novo* when it could not have conducted such a trial in the first instance").

14. The *Freytag* Court granted certiorari under *Glidden Co. v. Zdanok*, 370 U.S. 530, 535-536 (1962) which "expressly included Appointments Clause objections to judicial officers" as "structural constitutional objections that could be considered on appeal whether or not they were ruled upon below." *Freytag, supra*, at 878-79.

inconsistency. Each master utilizes his or her own standard. *Stevens, supra,* 2001 WL 387418 at *12 (the "more appreciable factor" in the disparate results of the Program "is the various legal standards that the special masters employ"). The master herein, as noted by dissenting Judge Dyk (App. 68-App.75 *infra*), created an new "essential element" in the causation test. It is one which has been disapproved by the Court of Federal Claims, in another "nonprecedential" ruling[15].

The government prevailed in *Pafford* without firing a shot: without raising any alternate cause defenses, without pleading the pivotal "defense," and without even suggesting alternate causation. Yet, once the master concocted findings contrary to unanimous medical opinion in this case, it became impossible for Richelle Pafford to obtain a day in court before an appointed judge, to challenge the master's own unpleaded defense[16] to her otherwise meritorious petition.

The Vaccine Program's adjudicative blueprint, adapted from European civil law tradition, fails to comport with American principles of procedural Due Process. Its tolerance for disparate results overtly denies Equal Protection, and the jurisprudential design of the Vaccine Program allows identical cases to arrive at disparate results. Persons who could not obtain compensation in the Vaccine Program have

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15. The Court of Federal Claims holds that "[s]pecial masters are neither bound by their own decisions nor by cases from the Court of Federal Claims." *Hanlon v. Secretary of DHHS,* 40 Fed.Cl. 625, 630 (Fed.Cl. 1998). This means that under *Bazan v. Secretary of DHHS*, 70 Fed.Cl. 687, 693 (2006) a Program petitioner identically situated with Richelle Pafford will have the benefit of a rule of law that "respectfully disagrees" with *Pafford.*

16. Depending on the rule of law chosen by an individual special master, a Program petitioner who does not rule out alternate cause may still—unlike Richelle Pafford—be held to have demonstrated a *prima facie* case for compensation. Judge Dyk's dissent demonstrates the statutory error in the contrary, on-and-off-again rule. *See also Stevens, supra,* 2001 WL 387418 at *12 ("disparate treatment of similarly-situated petitioners . . . . involves not only what type or combination of evidence supports petitioner's claims, but the scope of petitioner's burden as well").

been identically situated with those whose petitions have been accepted.

The Due Process analysis by the Court of Federal Claims and the Federal Circuit in this case is contrary to every significant pronouncement of this Court and the other Circuits Courts of Appeal, with regard to the essential need for apprisal of issues and the notice that must precede a meaningful opportunity to be heard. The standard for vaccine cases is overtly contrary to the requirements of the Administrative Procedures Act. The instant case, for instance, portends that no defense is ever waived, and that failure to adequately anticipate that unpleaded issues will be dispositive is simply a petitioners' tough luck.

A sweeping, remedial exercise of this Court's supervisory jurisdiction is necessary. Vaccine Act adjudication departs radically, egregiously, from the accepted and usual course of judicial proceedings. Manifestly unjust results like the one below are common, yet frequently are validated by the exceedingly deferential reviewing courts. The only way to save the constitutionality of the Vaccine Act is to nullify its unconstitutional standard of review, and to impose upon it the strictures and procedural protections of the Administrative Procedures Act.

Moreover, a rule of *stare decisis* must be implemented, and the quasi-judicial anarchy created by the masters and allowed by the Federal Circuit must be replaced with ascertainable legal standards. The system must be required to equally apply a test for causation—and for pleading and proof—in all cases.

A. THE SPECIAL MASTERS ARE VESTED WITH MORE POWER THAN THE CONSTITUTION ALLOWS FOR "INFERIOR OFFICERS" OF THE UNITED STATES

The National Childhood Vaccine Injury Compensation Act of 1986 was passed as Public Law 99-660. This "Vaccine Act" provided for petitions to be filed in federal district courts.

The federal district court, an Article III judicial tribunal, would then "designate" a special master to audit the record, and enter judgment on the basis of the master's report. *See, generally,* H.R. Report 99-908, 99th Cong., 2nd Sess., Sept. 26, 1986, *reprinted* 1986 U.S.C.C.A.N. 6287[17].

A master "designated" to review a vaccine injury claim was to be an "adjunct" to the federal district court under the original § 300aa-12 (c) (2) (1986). However, before the Vaccine Program was funded and effective as of November 15, 1988, Congress had been persuaded to grant jurisdiction over vaccine injury to the United States Claims Court, an Article I "legislative" tribunal[18]. Nonetheless, even then the provisions of § 300aa-12 (d) (1) (1988) provided that the Claims Court would have the power to undertake *de novo* review.

Anticipating the effective date of the Act, the Claims Court "designated" special masters by staffing a full-time office, and the current Chief Special Master was appointed at that time. But very soon after the Program was up and running, Congress became distraught with how "adversarial" the process had become[19]. Thus, in 1989 Congress enacted "technical corrections," as "Miscellaneous Health Related

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17. This original legislative intent document features "section-by-section analysis and discussion" of the compensation provisions, §§ 300aa-10 *et seq.*, starting at p. 13 (*reprinted* 1986 U.S.C.C.A.N. p. 6354). Section 2112 (the original § 300aa-12), granting jurisdiction to the district courts, is described in detail at pp. 16-18 (*reprinted,* 1986 U.S.C.C.A.N. pp. 6357-59).

18. The Federal Courts Improvement Act of 1982, Public Law 97-164, split the venerable Court of Claims into the new, Federal Circuit Court of Appeals, and the "United States Claims Court"—an Article I court by express designation. 28 U.S.C. § 171 (a). The Federal Circuit, an Article III judicial body, immediately adopted the Rules of Decision from the now-defunct Court of Claims as its own, and affords *stare decisis* to such decisions.

19. The legislative intent document that includes the "Vaccine Compensation Technicals" of 1989 is H.R. REP. 101-247, pp. 509-519, *reprinted* 1989 U.S.C.C.A.N. 1906, 3112-3122.

Provisions" under section 6601, Subtitle D of the Omnibus Budget Reconciliation Act, Public Law 101-239. A "technical amendment" to establish the Office of the Special Masters under section 300aa-12 only codified the pre-existing "office" and its already-filled positions.

However, the so-called "technical" amendment also abolished the *de novo* standard of review, and enacted a new, deferential standard under section 300aa-12(e)(2), expressed in concepts taken from the Administrative Procedures Act. And while the Court of Federal Claims would have jurisdiction (for 120 days) to issue its own findings of fact and conclusion of law on the record, no power to receive evidence is granted in the amended statute[20].

This petition requires review by virtue of what Justice Harlan called "the strong interest of the federal judiciary in maintaining the constitutional plan of separation of powers." *Freytag, supra,* 501 U.S. at 879 (concluding that "this is one of those rare cases in which we should exercise our discretion to hear petitioners' challenge to the constitutional authority" of the presiding quasi-judicial officer).

This Court has **never** approved a Congressional grant of unbridled authority to make a final decision, when such power has been vested in "inferior officers" which the Courts of Law or the heads of agencies are empowered to hire under the Appointments Clause. The "technical" amendment to create the Office of the Special Masters literally gave that office quasi-judicial agency status, without requiring that the agency head—or heads—be appointed by the President with the advice and consent of the Congress.

The masters are given such sway in adjudicating the government's liability as to functionally define them as

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20. The Act when it was new featured a general unseverability provision as a note to § 300aa-1. If any portion was found unconstitutional the entire Act would fall. An amended version (*infra,* App. 82) created an exception for the 1989 technical corrections and provided in the event of unconstitutionality that the Act as it had been before technical amendment would "continue in effect."

"principal officers" of the United States. *See, generally, Edmond v. United States,* 520 U.S. 651 (1997). The masters are empowered "to render a final decision on behalf of the United States" and have that power **whether or not** they are "permitted to do so by other Executive officers." *Id.,* p. 665. This is contrary to the Appointments Clause, and egregiously violates Separation of Powers principles.

The power of a Court of Law to make *de novo* determinations has always been essential to the validity of the appointment of a subordinate official of that court. *See, United States v. Raddatz,* 447 U.S. 667 (1980). The Office of the Special Masters as created under the 1989 technical amendments to the Vaccine Act is unconstitutional.

At a minimum, "[w]hat is needed . . . is a detailed look at the powers and duties of these judges to see whether reasons favoring their inferior officer status within the constitutional scheme weigh more heavily than those to the contrary." *Edmond, supra,* 520 U.S. at 668 (Souter, J., concurring). *See also Morrison v. Olson,* 487 U.S. 654 (1988)[21] and *Weiss v. United States,* 510 U.S. 163, 183-185 (1994) (Souter, J., concurring)[22].

The "inquisitorial" aspect of the Office of the Special Masters is a function both legislative and judicial, and makes inroads upon the executive function of the Attorney General, whose responsibility it is to "conduct litigation." The scope of powers is such as to be only proper—if at all—when vested in "Officers of the United States." *See, Buckley v. Valeo,* 424 U.S. 1, 124-137 (1976).

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21. Justice Scalia's *Morrison* dissent (487 U.S. at 697, 716) explains how the masters are not on the "inferior officer" side of the Appointments Clause. The opinion also invokes the basic and fundamental principle of American government violated by the Vaccine Act's grant of legislative, executive **and** judicial power to masters: The Program is a government of men, and not of laws.

22. The Court will note, for instance, the provisions of § 300aa-12 (c) (2) whereby masters cannot be discharged except for good cause. (App. 84, *infra.*)

B. THE "INQUISITORIAL" FEATURES OF ADJUDICATION UNDER THE VACCINE ACT DENY DUE PROCESS OF LAW, BY EMPOWERING MASTERS TO ABJURE TRIAL-TYPE PROCEDURE

In the case at bar, no burden—not even of pleading or production—was placed on the government. The "inquisitorial" master went out of his way to investigate the petitioners' theory that vaccines "can cause" the injury alleged, using Internet research[23] to expound on the mechanism of injury. But then the master used a barely disputable issue as the *sine qua non* of a sufficient causation case, and failed to lift even a finger to investigate the premise he alone decided to raise. And the "issue"—never pleaded, and arguably conceded—then became appeal-proof, as the Court of Federal Claims found that reading the inquisitorial tribunal's mind is the petitioners' "traditional task" of "meeting the respective burden of proof." The notion that issues may be raised *sua sponte* was regarded as a matter of "discretion." (App. 48-App. 50, *infra*.) And that petitioners could be deprived of the inferences to which they would be entitled in **any** truly judicial, rules-based tribunal—relying on an unrebutted presentation—was of no moment.

Over the several decades of this Court's jurisprudence

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23. One recent Court of Federal Claims review opinion severely criticizes unannounced reliance on Internet articles. In *Campbell ex rel. Campbell v. Secretary of DHHS*, 69 Fed.Cl. 775, 779 -781 (2006) the court observed that "the Special Master relied on these materials not at her risk, but at ***petitioners'*** risk." *Id.*, p. 781, emphasis in the original. This rare ruling is mandated by Due Process. *See*, Rule 201 F.R.E. ("Judicial Notice of Adjudicative Facts"), where subsection (c) mandates that a party is entitled to be heard as to the propriety of taking judicial notice and the tenor of the matter noticed, and in the absence of prior notification, such request may be made after judicial notice has been taken. *See also* 1972 Advisory Committee Note to subsection (b), citing and quoting Davis, "A System of Judicial Notice Based on Fairness and Convenience," Perspectives of Law 69, 93 (1964).

in the age of the executive agency, the requirement of Due Process in adjudication has been jealously protected by the federal courts. The duty to "fairly listen to both sides" is imposed upon "every one who decides any thing." *Joint Anti-Fascist Refugee Committee v. McGrath* 341 U.S. 123, fn. 17 at 170 (1951). This Court has held that the "elementary and fundamental requirement of due process in any proceeding which is to be accorded finality is notice reasonably calculated, under all the circumstances, to apprise interested parties of the pendency of the action and afford them an opportunity to present their objections." *Mullane v. Central Hanover Trust Co.,* 339 U.S. 306, 314 (1950). In *Mathews v. Eldridge,* 424 U.S. 319, 335 (1976), this Court ruled that the determination of "what process is due" turns on a balancing of three factors: "[f]irst, the private interest that will be affected by the official action; second, the risk of an erroneous deprivation of such interest through the procedures used, and the probable value, if any, of additional or substitute procedural safeguards; and finally, the Government's interest, including the function involved and the fiscal and administrative burdens that the additional or substitute procedural requirement would entail." The Federal Circuit has consistently ignored this test in vaccine matters, and the Court of Federal Claims likewise. Nothing has ever been presented to these courts to suggest that it would be impractical or prejudicial to a concrete public interest **not** to afford the opportunity to be heard before and adverse decision in such as case as Richelle Pafford's[24]. The touchstone of the decisions in the Program is simply the unbridled discretion that Congress granted under the "inquisitorial" format.

The result below places the Federal Circuit alone

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24. The petitioners' interest in a vaccine petition is in obtaining the just compensation—a statutory benefit—that will prevent a life of hardship and dependency. The risk of erroneous deprivation via procedural shortcut is substantial. And no burden not already borne by the Program, nor borne every day in every court in the land, would inure by virtue of APA protections.

among the Circuits regarding the resolution of unpleaded issues. No other Circuit repudiates a litigant's right to be reasonably "apprised" of the issues that will underlie a decision. *See, e.g., Henry Bierce Co. v. N.L.R.B.*, 23 F.3d 1101, 1108 (6th Cir. 1994) (where a party upon adequate notice could have presented additional witnesses and evidence, it is "hard to conclude . . .[that it] suffered no prejudice and had a full and fair opportunity to litigate the question"); *State of Wyoming v. Alexander*, 971 F.2d 531, 543 (10th Cir. 1992) (by deciding the case "on the basis of a factor never previously put in issue" an agency violates "the guarantee of adequate notice on 'the matters of fact and law asserted'" to which a party must respond); *Golden Grain Macaroni Co. v. FTC*, 472 F.2d 882, 886 (9th Cir.1972), *cert. denied*, 412 U.S. 918 (1973)(noting that "if an issue was not litigated, and the party proceeded against was not given an opportunity to defend himself, an adverse finding on that issue by the agency . . . violate[s] due process").

In short, "[t]he right to a hearing embraces not only the right to present evidence, but also a reasonable opportunity to know the claims of the opposing party and to meet them. The right to submit argument implies that opportunity; otherwise the right may be but a barren one." *Morgan v. United States*, 304 U.S. 1, 18-19 (1938).

The Vaccine Program and its deferential reviewing courts have thus denied every protection required by federal courts in order to make agency actions fair, and their authors accountable. Congress had no intention of creating the litigious, protracted Program it received, simply by empowering the masters to seek, on their own, the support that a petitioners' case might need. The petitioners herein were subjected to trial, as have been hundreds of petitioners in the Program, simply on the pontifical assertion that their case was not sufficient proof of causation. The issue which was pivotal was never disclosed or litigated. But the so-called "discretion" of the master was held throughout to be a valid substitute for the orderly procedures of adversarial process.

Basic principles of administrative law counsel that the

"inquisitorial" format must yield to an adversarial format, as a matter of fundamental fairness, in any case where material disputes of fact must be resolved. An agency official who "investigates," yet conducts a hearing, must make his fact-findings "open to challenge and opposing evidence." *Crowell v. Benson*, 285 U.S. 22, 48 (1932). This is so even if the tribunal "is not bound by the rules of evidence which would be applicable to trials in court or by technical rules of procedure." To dispense with such protection infringes upon substantial rights. *Ibid.*

This Court has reiterated on several occasions the *dicta* from *Bowman Transp., Inc. v. Arkansas-Best Freight System*, 419 U.S. 281, 288 n.4 (1974), which describes the essential attributes of fair agency adjudication:

> "A party is entitled . . . to know the issues on which decision will turn and to be apprised of the factual material on which the agency relies for decision so that he may rebut it. Indeed, the Due Process Clause forbids an agency to use evidence in a way that forecloses an opportunity to offer a contrary presentation."

Just as importantly, the party before an agency has the right to know of the law that will be applied, especially if it will not be the law previously applied[25]. *See, e.g., Hatch v. Federal Energy Regulatory Commission*, 654 F.2d 825 (D.C. Cir. 1981). And the evolution of Program doctrine seems always to disadvantage the petitioner. Prior to the master's Decision below, no problem had **ever** been encountered with

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25. The Federal Circuit's *Althen* and *Capizzano* decisions are the latest of only a small handful of decisions to address the standard of causation. An earlier case, *Shyface v. Secretary of DHHS*, 165 F.3d 1344 (Fed.Cir.1999), adopted the "legal causation" standard of the Second Restatement of Torts. However, as noted by Judge Block (App. 52, *infra*) and in Judge Dyk's dissent below (App. 75-App. 78), the struggle continues to allocate the burdens of pleading and proof. The tribunals below have not even conclusively ruled whether the burden is on petitioners or the government to plead and prove the role—or lack thereof—of potential alternate causes under § 300aa-13 (a) (1) (B).

the "time frame" element, which the Chief Special Master in *Stevens* had referred-to as "easily satisfied[26]."

The Chief Special Master wrote his *Stevens* opinion in the effort to deal with "inconsistent findings and disparate treatment of petitioners." *Id.*, 2001 WL 387418, pp. *11 *et seq*. This Court must act to do away with these unfair and oppressive aspects of the vaccine injury adjudication system. The system fails to comport with the "basic human claim that the law should provide like treatment under like circumstances." Friendly, Federal Administrative Agencies, 19 (1962).

This Court must enforce the "qualified role" for *stare decisis* it recognized in *N. L. R. B. v. Wyman-Gordon Co.,* 394 U.S. 759, 766 (1969). It must enforce, as the federal court have been scrupulous to do in agency matters, a "duty of consistency" toward similarly situated petitioners. *See, Sirbo Holdings, Inc. v. C.I.R.* 476 F.2d 981, 987 (2nd Cir. 1973). To do otherwise, and to countenance *ad hoc* formulation of the very legal test that must be satisfied, is to make the special master a legislator, as well as the investigator and ultimate arbiter.

CONCLUSION

After eighteen years of Program experience, it is clear that vaccine injury litigation always has been and will continue to be adversarial. An "inquisitorial" judicial officer has no proper function in an adversarial system, and Program proceedings ineluctably lead to injustice. On proper briefing, this Court must reverse the misbegotten decision below, and declare unconstitutional those aspects of the Vaccine Act that frustrate fairness. The Court should install the procedural rules that enable American citizens to obtain a fair shake from administrative tribunals. Central to this task is the

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26. "In practice, this prong has proven easily satisfied as the experts are cognizant of and routinely testify to medically accepted time frames for the onset of injuries." *Stevens, supra*, 2001 WL 387418 at *26.

restoration of the judicial power of the properly-appointed judges of the United States Court of Federal Claims.

Respectfully submitted this 22nd day of January, 2007.

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Appendix A

United States Court of Federal Claims
Office of the Special Masters

LISA ANN PAFFORD AND RICHARD LEON PAFFORD PARENTS AND NEXT FRIENDS OF RICHELLE LORRAE PAFFORD, a minor,	)	
Petitioners,	)	
v.	)	No. 01-0165V
SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,	)	
Respondent.	)	

July 16, 2004.

Robert T. Moxley, Cheyenne, Wyoming, for Petitioners.
Melonie J. McCall, United States Department of Justice, Washington, D.C., for Respondent.

ENTITLEMENT DECISION

ABELL, J.

I. ISSUE

The Court held an entitlement hearing in this case on 8 July 2003. Petitioners allege that the DTaP, MMR and OPV vaccinations, or any component thereof, administered to Richelle Pafford (hereinafter "Richie") on 24 March 1998 resulted in the onset of systemic onset Juvenile Rheumatoid Arthritis, also known as Still's disease. The issue before this Court is simply whether Petitioners' allegation is correct.

However, the Court's arrival at its decision was anything but simple. The novel medical theory put forth by Petitioners and their experts created a Serbonian bog of unexplored territory. After wading through and coming out the other side, the Court cannot conclude that Richie's Still's disease was in-fact caused by the vaccinations at issue.

II. PROCEDURAL BACKGROUND

Petitioners have satisfied the requirements for a prima facie case pursuant to § 300aa-11(b) and (c) by showing that: (1) Petitioners are valid legal representatives; (2) the vaccines at issue are vaccines set forth in the Vaccine Injury Table; (3) the vaccinations were administered to Richie in the United States; (4) no one has previously collected an award or settlement of a civil action for damages arising from the alleged vaccine-related injury; and, (5) no previous civil action has been filed in this matter. Additionally, the § 300aa-16(a) requirement that the petition be timely filed has been met.

On 8 July 2003, the Court conducted an evidentiary hearing in this matter. The Court heard testimony from Petitioners' medical experts, Dr. Alan S. Levin [FN1] and Dr. Mark R. Geier, [FN2] and Respondent's medical experts, Dr. Carlos D.

FN1. Dr. Alan S. Levin earned an M.D. from the University of Illinois (Chicago Medical Center). He is board certified in pathology-- clinical pathology and board certified in allergy and immunology. Dr. Levin currently serves as an attending physician in the Department of Medicine at the Mount Zion and University of California San Francisco Hospitals. Dr. Levin has published more than sixty five full length articles and forty five abstracts in peer reviewed medical literature primarily concerning the subjects of immunology, immunopathology, cancer biology, and treatments. Dr. Levin also earned a J.D. from Golden State University and, along with his medical practice, has his own private law practice.

FN2. Dr. Mark R. Geier is a geneticist and an obstetrician but is not board certified in the areas of rheumatology, pathology, or immunology, which are at issue in this case. Although the undersigned will, within reason, hear any expert that a petitioner wishes to present, the weight of those experts opining outside of their areas of expertise will be accorded significantly less weight. Because Dr. Geier testified in matters to which his professional background is unrelated, his testimony is of limited value to the court. Notwithstanding such, Dr. Geier opined that the rubella virus contained in the MMR vaccine can produce chronic infection in synovial tissue resulting in the onset of JRA.

(continued...)

Rose, [FN3] Dr. Melvin Berger [FN4] and Lawrence H. Moulton. [FN5] The hearing transcript was filed on 8 August 2003.

Thereafter, the parties filed post-hearing briefs. On 8 October 2003, Petitioners filed their post-hearing brief. On 22 December 2003, Respondent filed a post-hearing brief. Petitioners filed their sur-response on 9 February 2004. Thus, the record is complete and ripe for decision.

(...continued)

Transcript at 67. Dr. Geier stated that proof of such would be the presence of the rubella virus in the synovial fluid. *Id.* at 67-68. Regrettably, "the rubella virus was not isolated in any of [Richie's] synovial fluid" because "[n]obody looked." *Id.* at 128. Thus, Dr. Geier's theory, whether plausible or not, cannot be tested in this case and, therefore, will not be considered. Additionally, this Court is concerned at the apparent Procrustean application of Dr. Geier's theory which has been argued on four separate occasions before four separate special masters who, in each case, denied entitlement. *Poulos v. Sec'y of Health and Human Services*, 1994 WL 470622 (Fed.Cl.1994); *Carter v. Sec'y of Health and Human Services*, 1990 WL 293453 (Cl.Ct.1990), aff'd, 21 Cl.Ct. 651 (1990); *Muchnik v. Sec'y of Health and Human Services*, 1991 WL 217673 (Cl.Ct.1991); and, *Boehmer v. Sec'y of Health and Human Services*, 1991 WL 242995 (Cl.Ct.1991).

FN3. Dr. Carlos D. Rose is board certified in adult and pediatric rheumatology. Dr. Rose graduated summa cum laude from the University of Buenos Aires School of Medicine. Dr. Rose is a staff physician in pediatric rheumatology at The Alfred I. duPont Institute of the Nemours Foundation in Wilmington, Delaware and is a pediatric rheumatology consultant at the Medical Center of Delaware. Additionally, Dr. Rose served as a consultant to the National Institute of Health by providing expertise concerning the issue of rubella vaccine induced arthritis. He is also a member of the American College of Rheumatology.

FN4. Dr. Melvin Berger is board certified in pathology, board certified in pediatrics and board certified in allergy and immunology. Dr. Berger received an M.D. from Case Western Reserve University as well as a Ph.D. in Biochemistry. Dr. Berger currently serves as a professor in pathology and pediatrics at Case Western Reserve University and is the Chief of the Allergy/Immunology/Rheumatology Division, Department of Pediatrics at the Rainbow Babies and Children's Hospital.

FN5. Lawrence H. Moulton, Ph.D., is a biostatistician and a faculty member at Johns Hopkins Bloomberg School of Public Health, where he earlier earned his Ph.D. Dr. Moulton earned a bachelor's degree in both statistics and mathematics at the State University of New York at Buffalo and a master's degree at the Texas School of Public Health.

III. FACTS

Richie was born on 30 January 1993. Petitioners' Exhibit (hereinafter "Pet. Ex.") 1 at 6. She consistently received medical care from Dr. Jay Schmidt throughout her early childhood and there was nothing remarkable about Richie's early development. On 5 August 1993, during a well child exam, Dr. Schmidt administered Richie's first DTP, OPV and Hib vaccinations. Pet. Ex. 3 at 58. On 21 October 1993, Richie received her second DPT, OPV and Hib vaccinations. Id . at 53. On 10 May 1994, Richie had a normal well child exam and Dr. Schmidt noted normal development. *Id.* at 46. During the exam, Dr. Schmidt administered Richie's third DTP, MMR and OPV vaccinations as well as her first MMR vaccination. *Id.* On 27 May 1994, Richie developed a faint maculopapular [FN6] rash on the face, legs and arms that persisted for five days with a negative strep throat culture. *Id.* at 44-45.

During November and December 1997, Richie was treated for otitis. [FN7] *Id.* at 16-20. On 5 March 1998, Richie saw Dr. Schmidt complaining of a cold and diarrhea. *Id.* at 15. On 12 March 1998, Richie was seen by Dr. Schmidt for inflamed tonsils with white patches on them and a fever of 101-102 degrees Fahrenheit. *Id.* at 15. A resulting throat culture was negative for Streptococcus. [FN8] *Id.* at 13-15. On 24 March 1998, Richie had a normal examination showing normal growth and development with a history of normal activity including gymnastics. *Id.* at 11-12. Dr. Schmidt observed that her earlier tonsillitis had resolved, her neck was without

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FN6. "Both macular and papular. as an eruption consisting of both muscles and papules: sometimes erroneously used to designate papule that is only slightly elevated." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 971 (27th ed.1988). DORLAND'S at 1202.

FN7. "Inflammation of the ear. which may be marked by pain. fever. abnormalities of hearing. hearing loss. tinnitus. and vertigo." DORLAND'S at 1202.

FN8. "spherical gram-positive bacteria occurring in pairs or chains." http://www.cogsci.princet on.edu/cgi-bin/webwn?stage=1 & word=streptococcus.

lymphadenopathy, [FN9] her lungs were clear to auscultation, [FN10] a normal heart rate, a non tender abdomen, and no gross neurological deficits were noted. *Id.* at 11. Richie received a DTaP vaccination, her fourth OPV vaccination, and her second MMR vaccination that same day. *Id.* at 11. On 4 April 1998, Richie developed a fever and complained of neck pain. *Id.* 3 at 5. The next day, Richie's fever had abated but her neck pain continued. *Id.* Richie was taken to Dr. Schmidt's on 7 April 1998 for evaluation and treatment of her symptoms. *Id.* Richie had developed a diffuse pink, macular rash, whitish spots on her tongue (possible Koplik's spots [FN11]), and complained of limb pain that morning. *Id.* Richie was diagnosed with a vaccine-induced rash and was told to avoid exposure to other people for five days. *Id.*

On 13 April 1998, Richie was taken to the emergency room of the United Medical Center in Cheyenne, Wyoming. Pet. Ex. 5 at 1. She had a temperature of 103.9 degrees Fahrenheit, a blanching red maculopapular rash on the hands involving the palms and soles, on the medial aspects of her upper legs and on her chest and upper abdominal area. *Id.* at 8. Richie was vomiting at intake and refused all intake. *Id.* at 16. On initial examination in the emergency room, Dr. Valerie Bell noted that Richie was tearful and cried wherever touched. *Id.* at 16-17. Dr. Bell noted that "[t]he rash was very viral in character and I did not feel it was related to her

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FN9. "Disease of the lymph nodes." DORLAND'S at 960.

FN10. "The act of listening for sounds within the body, chiefly for ascertaining the condition of the lungs, heart, pleura, abdomen, and other organs, and for the detection of pregnancy." DORLAND'S at 169.

FN11. "Small, irregular, bright red spots on the buccal and lingual mucosa, with a minute blueish white speck in the center of each; seen in the prodromal stage of Measles." DORLAND'S at 1569.

immunizations but suggested a CBC [FN12] to see if it supported the viral picture." *Id.* at 16. By the time Richie was admitted, her temperature was 97.2 degrees Fahrenheit and her rash had greatly diminished. *Id.* She was "playful and happy" and had "no complaints whatsoever." *Id.* Richie tested positive for mycoplasma, [FN13] which Dr. Bell thought explained her symptoms at the time. Pet. Ex. 4 at 79. On her discharge the following day, Richie was afebrile and "her rash, for the most part, had disappeared." Pet. Ex. 5 at 9.

On 30 April 1998, Richie saw Dr. Bell for recurrence of fever and rash and complaints of increasing joint pain. Pet. Ex. 4 at 79. During the exam Dr. Bell recorded that Richie had a fever of 102.9 degrees Fahrenheit, a painful, swollen right elbow and left knee. *Id.* Neither of the joints, however, were red or hot. *Id.* The rash that Richie had on 13 April 1998 had returned. *Id.* It was "macular, reticular rash on her trunk slightly, prominent on hands, feet and lower legs, and on her thighs on the inner surfaces." Id . Dr. Bell "strongly suspected[ed] systemic onset JRA, as the cause of the month long recurrent rash, fever, and discomfort." *Id.* Richie's lab results revealed an elevated sedimentation rate of 80, mild anemia, and a negative ANA [FN14] and rheumatoid factor tests. *Id.* at 80.

Dr. Bell diagnosed Richie with systemic onset Juvenile Rheumatoid Arthritis, also known as Still's disease. *Id.* Richie was treated with Naprosyn [FN15] and prednisone [FN16]

FN12. "Complete blood count." Neil M. Davis. MEDICAL ABBREVIATIONS: 8600 CONVENIENCES AT THE EXPENSE OF COMMUNICATIONS AND SAFETY. 31 (6th Ed.1993).

FN13. "A bacterium of the class Mollicutes." DORLAND'S at 1085.

FN14. "Antinuclear antibody." MEDICAL ABBREVIATIONS at 15.

FN15. Naprosyn--a nonsteroidal anti-inflammatory drug (trade name Naprosyn) used in the treatment of arthritis and musculoskeletal inflammation and moderate pain.

(continued...)

with some benefit. *Id.* On 21 May 1998, this diagnosis was corroborated by Dr. Hollister, a pediatric rheumatologist at Children's Hospital in Denver, Colorado. *Id.* at 78. Attempts to wean Richie from the prednisone resulted in recurrent symptoms, and Methotrexate [FN17] was initiated in September 1998. *Id.* at 55-74.

On 28 January 1999, Richie had continued synovitis [FN18] despite maximum treatment with Methotrexate. *Id.* at 47. Due to the refractory nature of her Still's disease, it was recommended that a second level arthritis drug, Cyclosporin A, [FN19] be added to her medication regime. *Id.* at 48. It was determined that Richie would receive the varicella vaccine before starting the Cyclosporin A. *Id.* Over the next year, Richie's disease remained active with recurrent arthritis. *Id.* at 23-46.

IV. DISCUSSION AND ANALYSIS

1. What is Still's disease?

Still's disease is one type of juvenile rheumatoid arthritis ("JRA") and is also known as systemic-onset JRA ("soJRA").

(...continued)
http://www.cogsci.princeton.edu/cgi-bin/webwn?stage=1 & word=naprosyn.

FN16. Predinsone--a dehydrogenated analogue of cortisol (trade names Orasone or Deltasone or Liquid Pred or Meticorten); used as an anti-inflammatory drug in the treatment of arthritis and as an immunosuppressant. http://www.cogsci.princeton.edu/cgi-bin/webwn?stage=1 & word=prednisone.

FN17. Methotextrate–toxic antimetabolite that limits cellular reproduction by acting as an antagonist to folic acid; used to treat certain cancers and psoriasis and rheumatoid arthritis. http:// www.cogsci.princeton.edu/cgi-bin/webwn?stage=1 & word=Methotextrate+.

FN18. "Inflammation of a synovial membrane." DORLAND'S at 1649.

FN19. Cyclosporin A is the first of the new generation of immunosuppressive agents with a specific site of action within immune system. http://www.nrdcindia.com/pages/sporin.htm.

By systemic it is meant that along with joint inflammation it typically begins with symptoms and signs of systemic (body wide) illness, such as high fevers, gland swelling, and internal organ involvement. [FN20] It affects children inflaming the large joints and sometimes retarding bone growth. [FN21] Mostly, it involves an inflammation of the connective tissue. [FN22] A dispositive etiology is unknown, but like many other types of arthritis, abnormal immune response, genetic predisposition and environmental triggers, and infectious agents are all being considered. [FN23]

Still's disease usually begins with systemic symptoms. Extreme fatigue can accompany waves of high fevers that rise daily to 102 degrees Fahrenheit or even higher and rapidly return to normal levels or below. Fever spikes often occur at nearly the same time every day. A faint salmon-colored skin rash characteristically comes and goes and does not itch. Arthritis, with joint swelling, often occurs after rash and fevers have been present for some time. Although the arthritis may initially be overlooked because of the impressive nature of the systemic symptoms, everyone with Still's disease eventually develops joint pain and swelling. [FN24]

2. Were one or more of the 24 March 1998 vaccinations the cause of Richie's Still's disease?

Petitioners can prove entitlement to compensation under the Program in one of two ways. They can prove entitlement through a statutorily prescribed presumption of causation or,

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FN20. http://www.stillsdisease.org/still's_disease_info.htm.

FN21. http://www.cogsci.princeton.edu/cgi-bin/webwn?stage=1 & word=still.s+disease.

FN22. http://www.dynomed.com /encyclopedia/encyclopedia/arthritis/Juvenile_Rheumatoid_Arthritis.html.

FN23. http://arthritisinsight.com/medical/disease/stills.html.

FN24. http://www.medicinenet.com/Stills_Disease/pagel.htm.

by proving causation-in-fact. First, Petitioners may prove that Richie suffered an injury or condition listed in the Vaccine Injury Table within the statutorily prescribed time period. § 11(c)(1)(C)(i). If Petitioners establish that Richie suffered such injury by a preponderance of the evidence, Petitioners are entitled to a presumption of causation. § 13(a)(1)(A). If Richie qualifies under this presumption, she will be said to have suffered a "Table injury." The burden would then shift to the Respondent to prove that the injury or condition "is due to factors unrelated to the administration of the vaccine described in the petition." § 13(a)(1)(B).

If Petitioners fail to satisfy the requirements under the Act for demonstrating a Table injury, Petitioners may prove by a preponderance of the evidence that the vaccination in question, more likely than not, caused the alleged injury. §§ 11(c)(1)(C)(ii)(I) and (II). This causation-in-fact standard, according to the Federal Circuit, requires proof of a "logical sequence of cause and effect showing that the vaccination was the reason for the injury." *Grant v. Secretary of HHS* , 956 F.2d 1144, 1148 (Fed.Cir.1992). Once again, if Petitioners are successful in that showing, the burden shifts to Respondent to prove that the injury or condition "is due to factors unrelated to the administration of the vaccine described in the petition." § 13(a)(1)(B).

In the present case, Petitioners do not allege that Richie suffered a Table injury. Petitioners allege Richie suffered Still's disease as a result of one or more of the vaccinations she received on 24 March 1998. The Table does not list Still's disease as a recognized adverse event that warrants presumption, thus, Petitioners' claim is one of causation-in-fact. [FN25]

a. Causation-In-Fact

In order to demonstrate entitlement to compensation in a causation-in-fact claim, a petitioner must affirmatively demonstrate by a preponderance of the evidence that the

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FN25. 42 C.F.R. § 100.3(a).

vaccination in question more likely than not caused the injury alleged. See 11(c)(1)(C)(ii)(I) and (II); *Grant v. Secretary of HHS*, 956 F.2d 1144 (Fed.Cir.1992); *Strother v. Secretary of HHS*, 21 Cl.Ct. 365, 369-70 (1990), *aff'd*, 950 F.2d 731 (Fed.Cir.1991). The Federal Circuit, which summarized the legal criteria required to prove causation-in-fact under the Vaccine Act, requires that every petitioner: show a medical theory causally connecting the vaccination and the injury. Causation in fact requires proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury. A reputable medical or scientific explanation must support this logical sequence of cause and effect. *Grant*, 956 F.2d at 1148 (citations omitted); see also *Strother*, 21 Cl.Ct. at 370.

This Court has organized the legal criteria in *Grant* by means of a two-part test. First, a petitioner must provide a reputable medical theory causally connecting the vaccination and the injury. In fine, can vaccine(s) at issue cause the type of injury alleged? Second, a petitioner must also prove that the vaccine actually caused the alleged symptoms in her particular case. Under the first prong, a petitioner must demonstrate the biologic plausibility of their theory by proffering a scientific pathogenesis underlying the alleged causal relationship. This may be accomplished in a number of ways. Reliability and plausibility of that pathogenesis can be bolstered by providing evidence that at least a sufficient minority in the medical community has accepted the theory as to render it credible. In addition, epidemiological studies and an expert's experience, while not dispositive, [FN26] lend significant credence to the claim of plausibility. Articles published in respected medical journals, which have been subjected to peer

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FN26. This first prong of the Court's test meets easily with cases where epidemiological or case study reports are already available. Beginning with this prong is practical when there is epidemiological evidence, for it avoids the tautological reasoning that would result when one attempts to answer Can It? without having reports and studies that previously would have answered Did It?

review, are also persuasive. However, publication "does not necessarily correlate with reliability," because "in some instances well-grounded but innovative theories will not have been published." *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U .S. 579, 593-94 (1993).

The second prong of the causation-in-fact test is difficult to meet but not impossible. A petitioner must show, by a preponderance of the evidence—as this special master is wont to say, a test based on fifty percent and a feather—that the vaccine caused the injuries or symptoms that manifested in this case. A petitioner does not meet this affirmative obligation by merely showing a temporal association between the vaccination and the injury. If petitioners' expert views the temporal relationship as the "key" indicator of causation, the claim must fail. *Thibaudeau v. Sec'y of the HHS*, 24 Cl.Ct. 400, 403 (1991). Rather, a petitioner must explain how and why the injury occurred. *Strother*, 21 Cl.Ct. at 370; see also *Hasler v. United States*, 718 F.2d 202, 205 (6th Cir.1993), cert. denied, 469 U.S. 817 (1984) (stating that inoculation is not the cause of every event that occurs within a ten day period following it). Ruling out other potential causes is an essential element but does not itself establish causation. Additionally, mere conjecture or speculation does not meet the preponderance standard.*Snowbank Enterprises v. United States*, 6 Cl.Ct. 476, 486 (1984)

b. Applicability of the Two Part test in Richie Pafford's Case

In Richie's case, the Court follows the two pronged causation in fact analysis tailored as: (i) Is it biologically plausible that one or more of the vaccinations in question can cause Still's disease?; and, (ii) Did one or more of Richie's vaccinations result in her Still's disease? (i) Is it biologically plausible that one or more of the vaccinations in question can cause Still's disease?

Petitioners' expert, Dr. Levin and Respondent's expert, Dr. Rose, both agreed that an individual that develops Still's disease generally has a genetic predisposition to do so. Transcript (hereinafter "Trans.") at 171, 172, 469 and 471. However, Dr. Berger, another medical expert appearing for

Respondent, while not ruling out the possibility of a genetic predisposition, was unwilling to conclude that such was absolutely necessary in contracting Still's disease. *Id.* at 423. Dr. Levin opined that this predisposition can be triggered by vaccinations, Trans. at 171, resulting in an autoimmune [FN27] mediated inflammatory disorder known as the "activation of a forbidden clone." [FN28] Pet. Ex. 8 at 3. Dr. Levin asserted that the activation of the forbidden clone is an inflammatory response "causing the release of cytokines [FN29] which drive the expression and expansion of cells with autoreactive anti-self activity." *Id.* at 2. Dr. Levin went on to state that "[i]t is well recognized that the symptoms of Still's disease are caused by cytokine expression." *Id.* at 3. According to Dr. Levin, the release of certain pro-inflammatory cytokines such as Interleuken [FN30] ("IL")-1, IL-4, and IL-6 trigger Still's disease. Trans. 173. Dr. Levin stated that this has been proven, in that when treating Still's disease, its symptoms can be alleviated by treating the patient with "that particular molecular which tends to be a sponge for certain cytokines," *Id.* at 174, thereby reducing or

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FN27. Autoimmunity: an abnormal condition in which the immune system develops antibodies against the body's own tissues, causing a reaction that results in an autoimmune disease. http://www.peppypaws .com/Glossary.html.

FN28. The Forbidden Clone Theory: a theory that at birth all cells that might react against the body have been eliminated, leaving only cells that will react against foreign substances; when cells that react against the body persist after birth, they can be activated by something and result in an autoimmune disease. http://www.peppypaws.com/Glossary.html.

FN29. Cytokine: "a generic term for non-antibody proteins released by one cell population on contact with a specific antigen, which act as intercellular mediators, as in the generation of an immune response." DORLAND'S at 427-28.

FN30. Interleukin: "a generic term for a group of protein factors produced by macrophages and T cells in response to antigenic or mitogenic stimulation and affecting primarily T cells." DORLAND'S at 845.

removing the cytokines.

Respondent's expert, Dr. Rose, agreed that "Still's disease has a lot of cytokines circulating," *Id.* at 468, and that IL-1, TNF Alpha, [FN31] and IL-6 are "all really big players in the observed symptoms of Still's disease." *Id.* at 462. Dr. Rose also added that treating Still's disease patients by trying to reduce certain cytokines "has produced a 70 percent success rate." *Id.* Finally, Dr. Rose testified that vaccines induce cytokine production. "Cytokines are produced by the host after receiving the vaccination. If vaccines could not induce cytokines, they could not induce immunity for you to protect against the infectious agent." Trans. at 463. Additionally, Dr. Berger stated that certain cytokines "are important mediators of Still's or systemic-onset JRA" and that it is a matter of excessive and prolonged cytokine production that results in the manifestations of the disease. *Id.* at 421.

Based on the testimony of Petitioners' expert, Dr. Levin and Respondent's experts, Dr. Rose and Dr. Berger, the Court finds that, by a preponderance of the evidence, it is biologically plausible that one or more of the vaccinations at issue could cause the onset of Still's disease. The experts agree that there is a genetic predisposition to the disease, that a hallmark of the disease is cytokine expression, [FN32] vaccines induce cytokine expression, and treating such expression reduces the disease's effects. [FN33]

FN31. "Tumor necrosis factor [("TNF")] alpha is a cytokine produced primarily by monocytes and macrophages." http://www.arthritis.co.za/tnf.htm.

FN32. "Abnormal expression of the three primary inflammatory cytokines (IL-6, IL-1, and TNF alpha) is characteristic of [systemic onset Juvenile Rheumatoid Arthritis]." Respondent's Exhibit L.

FN33. "The Special Master is not required to be a 'potted plant'.... Rather, the legislative history of the newly-amended Vaccine Act emphasizes that '[t]he system is intended to allow the proceedings to be conducted in ... an "inquisitorial" format, with the [special] master conducting discovery (as

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(...continued)
needed), cross-examination (as needed) and investigation.'" *Hines v. Sec'y. of Health and Human Services*, 21 Fed. Cl. 634, 648 (1990) (emphasis added). Accordingly, the Court, sua sponte, researched Dr. Levin's theory and found additional support for his assertions regarding the autoimmune mediated nature of rheumatoid arthritis:

One prevalent theory is that a combination of factors trigger rheumatoid arthritis, including an abnormal autoimmune response, genetic susceptibility, and some environmental or biologic trigger. The primary infection-fighting units are two types of white blood cells: lymphocytes and leukocytes. Lymphocytes include two subtypes known as T-cell s and B-cells. T-cells have special receptors attached to their surface that recognize the specific antigen. T-cells are further categorized as killer T-cells or helper T-cells (TH cells). Helper T-cells also recognize antigens, but their role is two fold. They stimulate B-cells and other white cells to attack the antigen. They also produce cytokines, powerful immune factors that have an important role in the inflammatory process. The actions of the helper T-cells are of special interest in rheumatoid arthritis. For some unknown reason, the T-cells become overactive in rheumatoid arthritis and mistake the body's own collagen as an antigen and trigger a series of immune responses to destroy the false enemy: TH-cells also secrete or stimulate the production of powerful immune factors called cytokines. In small amounts, cytokines are indispensable for healing. If overproduced, however, they can cause serious damage, including inflammation and injury in the joints during the rheumatoid arthritis process. They may even be responsible for inflammation that occurs in parts of the body beyond the joints, including fever, shock, and even damage to organs, such as the liver. Important cytokines in the destructive process of rheumatoid arthritis are those known as interleukins (ILs) and tumor necrosis factor (TNF). Researchers are specifically interested in interleukins 1, 6, 9, 10, 11, 12, 15, and 17. (Some of these, such as interleukin-10, may be protective.) Some cytokines play a role in releasing enzymes, such as those known as collagenase and cathepsin L, which destroy collagen. Genetic factors play some role in rheumatoid arthritis, but most experts believe that more than one gene collaborates in the process and that the disease still requires other factors to set it off. Although many bacteria and viruses have been studied, no single organism has been proven to be the primary trigger for the autoimmune response and subsequent damaging inflammation. http://www.ucdmc.ucdavis.edu/ucdhs/health/a-z/48RheumatoidArthritis/doc48causes.html.

"If lymphocytes produce antibodies or T cell receptors (TCRs) which recognize antigens in our own tissues, then these tissues will be attacked by the phagocytes and will suffer damage. When this happens then we say

(continued...)

(ii) Did one or more of the 24 March 1998 vaccinations in question cause Richie's Still's disease?

(A) Was there a logical sequence of cause and effect?

Dr. Levin testified that the link between the 24 March 1998 vaccinations and Richie's Still's disease is "real, real clear." Trans. at 193. Dr. Levin stated that one or more of the vaccinations administered on 24 March 1998 triggered Richie's genetic propensity to contract Still's disease. *Id.* at 171. This triggering caused an inflammatory response, marked by an increase in cytokine expression, resulting in the disease. *Id.* at 172. Dr. Levin stated that a number of things could have triggered the disease such as surgery or viral illness, *Id.*, but "the only factor that seems to be associated with the development of this disease process is the vaccination." *Id.* at 173. Thus, Dr. Levin opines that "[b]ased upon the strong temporal association between the exposure and the disease and in the absence of confounding factors" he believes "to a reasonable degree of medical certainty that the vaccinations that Michelle [sic] Pafford received on 3/24/98 triggered and caused her present autoimmune disorder (Still's disease)." Pet. Ex. 8 at 3.

When asked what specific agent in any one of the vaccines was responsible for triggering the reaction that allegedly led

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that the patient is suffering from an autoimmune (Auto--self) disease. It is precisely this scenario that we believe occurs in the autoimmune disease, rheumatoid arthritis. For some reason, which is yet to be discovered, those individuals who suffer from rheumatoid arthritis have immune systems that appear to recognize as foreign some constituents in their joints. B and T lymphocytes enter into the joint and in turn call in the phagocytes--polymorphs and macrophages--to the party. The entry of all these white blood cells into the joint produces a large number of cytokines which cause the joint to be painful, result in the joint becoming swollen and slowly cause the damage to the joint which leads it to become disfigured and unable to work properly. The joint damage is caused by the release of special proteins (called proteinases) which destroy the large molecules of which the articular cartilage and bone are composed." http://www.arc.org.uk/newsviews/arctdy/108/ cellsbells.htm (emphasis added).

to Richie's Still's disease, Dr. Levin could not answer. Dr. Levin testified that "I can speculate" as to which component "but that's as far as I can go, and I don't think anybody can give you a scientifically plausible answer in this particular case" as to which component triggered her reaction. Trans. at 219-20.

However, in his opinion letter filed on 16 April 2002, Dr. Levin asserts that "[i]t is also well established that immune activation caused by DPT vaccinations is in turn caused by the release of the very cytokines that are elevated in Still's disease." Pet. Ex. 8 at 3. This assertion is bolstered by medical literature referenced by Dr. Levin. "Whole-cell pertussis found in diphtheria-tetanus-pertussis (DTP) vaccine can produce symptoms reminiscent of biological responses to circulating proinflammatory monokines such as IL-6, IL-1 beta, and TNF alpha." Pet. Ex. 16 at 1. [FN34] Although DTP is not a vaccine at issue here, the administration of DTaP also results in enhanced IL-6, IL-1 beta, and TNF alpha stimulation, though resulting levels are less than that induced by DTP. *Id.* at 4. Thus, DTaP stimulates IL-6, IL-1 beta, and TNF alpha expression, which both parties' experts agree are part of the observed symptoms of Still's disease.

When addressing whether there was any evidence that Richie indeed had higher levels of cytokine expression, Dr. Levin explained that at the time of onset, the medical field had yet to develop testing sophisticated enough to identify specific cytokines. Trans. at 214. However, Dr. Levin stated that there were indirect tests performed which did correlate with the clinical symptomatology. *Id.* Specifically, on 13 April

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FN34. Jane Blood-Siegfried et al., Monokine Production Following in Vitro Stimulation of the THP-I Human Monocytic Cell Line with Pertussis Vaccine Components, 18 JOURNAL OF CLINICAL IMMUNOLOGY 81 (1998).

2004, Richie had a high white blood cell [FN35] count of 26,000, where the normal range is between 4,500 and 12,000 per mcl (microliter). Pet. Ex. 5 at 8; Pet. Ex. 4 at 73. White blood cells secrete cytokines [FN36] and, accordingly, a high white blood cell count may indicate a corresponding increase in cytokine expression. Trans. at 214.

(B) Temporal relationship?

Richie experienced some typical post-vaccinal side effects. [FN37] On 4 April 1998, eleven days after the administration of the vaccines at issue, Richie developed a fever and neck pain. Pet. Ex. 3 at 5. On her visit to Dr. Schmidt's on 7 April 1998, it was noted that Richie had developed a diffuse pink, macular rash, which subsided soon thereafter. *Id.*; Pet. Ex. 4 at 83. Dr. Schmidt noted that the rash appears to be vaccine

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FN35. White Blood Cell: "A blood cell that does not contain hemoglobin: a blood corpuscle responsible for maintaining the body's immune surveillance system against invasion by foreign substances such as viruses or bacteria. White cells become specifically programmed against foreign invaders and work to inactivate and rid the body of a foreign substance." http://www.diagnose-me.com/glossary/G788.html.

FN36. http://www.diagnose-me.com/glossary/G799.html.

FN37. "As with other vaccines, MMR can cause a local reaction with pain and induration at the injection site (CDC, May 1998). Because it is a live virus vaccine, mild illness with symptoms similar to measles, mumps or rubella may occur. About 7-12 days after vaccination, five percent of children develop a fever with temperature greater than 103 degrees, which lasts 1-2 days (Peltola & Heinonen in CDC, May 1998). A transient rash may occur 7-10 days post vaccination in 5 percent of children (due to the measles and rubella components). Transient lymphadenopathy (rubella component) and rare parotitis (mumps component) have also been described (CDC, May 1998)." http://www.corexcel.com/courses/body.immunizations.page9.htm.

Typical "[s]ide effects of the DTaP vaccine are mild and usually last for only a few days after getting the needle. Mild pain, swelling and redness are common at the spot where the needle was given. A few people may get a mild fever, upset stomach, body aches or feel tired for a day or two after the needle." http://www.mpshu.on.ca/Immunization/dTap.htm.

induced. *Id.* It was also noted that Richie was experiencing fatigue, her upper arm hurt and she had limb pain. *Id.* Thus, at least through the first week of April 1998, the symptoms that Richie experienced do not appear out of the ordinary.

The onset of Richie's Still's disease is apparent some time during the second week of April 2004. On 13 April 2004, Richie presented with a temperature of 103.9 degrees Fahrenheit, a blanching red maculopapular rash on the hands involving the palms and soles, on the medial aspects of her upper legs and on her chest and upper abdominal area. Pet. Ex. 5 at 1. By the time she was admitted to the hospital, her temperature had quickly subsided to 97 .2 degrees Fahrenheit and her rash had greatly diminished. Id at 16. Such temperature instability fits the profile of Still's disease. [FN38] Additionally, the transient nature of her rash is common to Still's disease. [FN39] On 30 April 1998, Dr. Bell noted a recurrence of fever (102.9 degrees Fahrenheit) and rash and complaints of increasing joint pain. Pet. Ex. 4 at 79. At that time, Dr. Bell, in conjunction with other doctors, concluded that Still's disease "is the most likely diagnosis." *Id.* at 80. His diagnosis was corroborated on 21 May 1998 by Dr. J. Roger Hollister, of the Children's Hospital, Rheumatology Clinic. *Id.* at 77.

Petitioner argues that the onset of Richie's Still's disease within a few weeks of the vaccinations at issue strongly suggests a connection between the two. Petitioners' Closing

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FN38. "Patients with Still's disease usually present with systemic (body wide) symptoms. Extreme fatigue can accompany waves of high fevers that rise to 104 degrees F (41 degrees C) or even higher and rapidly return to normal levels or below. A faint salmon-colored skin rash characteristically comes and goes and usually does not itch.... Although the arthritis may initially be overlooked because of the impressive nature of the systemic symptoms, everyone with Still's disease eventually develops joint pain and swelling. This usually involves many joints (polyarticular arthritis). Any joint can be affected, although there are preferential patterns of joint involvement in Still's disease." http:// stilligans.tripod.com/stills1.htm.

FN39. See note 38 supra.

Argument and Memorandum of Law (hereinafter "Pet. Clos. Arg.") at 1-2. [FN40] As stated supra, a temporal relationship between the alleged injury and the administration of the vaccine is not itself sufficient for Petitioners to meet their burden of proof by a preponderance of the evidence. However, as this Court has previously found, where the claimed injury's manifestation of onset falls within an established time period subsequent to an antecedent or triggering event, the timing of onset is telling. [FN41]

Here, Petitioners argue that Richie was genetically predisposed to contract Still's disease and that the 24 March 1998 vaccinations triggered its onset.

However, Petitioners provide no objective evidence indicating an appropriate time frame in which Still's disease will manifest subsequent to a triggering event. Thus, it appears, at least to this Court, that the timing of onset of Still's disease subsequent to a triggering event is not a telling characteristic of the disease. Accordingly, absent an appropriate time frame, the Court cannot find the mere temporal proximity of the vaccination and injury dispositive.

FN40. The Court is troubled by a portion of Petitioners' counsel's argument during the 7 July 2003 Entitlement Hearing that Richie does not meet the "American College of Rheumatology criteria for the diagnosis of definite systemic onset JRA." Pet. Ex. 56 at 76, and that Richie may have a "JRA-like illness." *Id.* at 77. Until that point in Petitioners' argument and subsequently in Petitioners' closing memorandum, Petitioners claim Still's disease. Pet. Clos. Arg. at 1-2. Thus, the Court is left perplexed by Petitioners' counsel's late equivocation and finds that it serves only to further cloud Petitioners' claim.

FN41. This case stands in contrast to the Court's reasoning in *Kuperus v. Sec'y of Health and Human Services* 2003 WL 22912885, 11 (Fed.Cl.2003) and *Brown v. Sec'y of Health and Human Services*, 01-0060V at 9 (unpublished). In these cases, the onset of Petitioner's injuries occurred within an appropriate time frame--as described by the medical experts and other objective medical evidence--such that the vaccinations could be considered triggering events.

[FN42]

(C) Were there possible alternative causes?

All experts agree that a number of things can trigger Still's disease. Respondent's experts posit that Richie's Still's disease could have been activated by any number of these triggers. However, Respondent puts forth no argument on behalf of any of these triggers beyond asserting their possibility.

Respondent's expert, Dr. Rose, testified that when a person, such as Richie, has a predisposition for Still's disease, "you may find a lot of potential triggers" for its onset "if you take a good history." Trans. at 466. The day Richie received the vaccinations at issue, the administering pediatrician noted that "[s]he is doing well" and "at the present time is suffering no symptoms of illness." Pet. Ex. 3 at 11. However, on the date of her hospital admission, 13 April 1998, Richie tested positive for mycoplasma. [FN43] Pet. Ex. 5 at 9. Dr. Berger testified that a positive test for mycoplasma could be "interpreted as meaning that she had a recent acute infection," Trans. at 364, and he posited that the mycoplasma

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FN42. The only objective evidence concerning the timing of onset subsequent to a preceding event was an exhibit filed by Respondent. Res. Ex. I. In the exhibit, the authors state that Reactive Arthritis is triggered by bacterial infection and that diarrhea within four weeks preceding onset is clear evidence of infection. *Id.* at 679. Therefore, at least in the case of Reactive Arthritis, one could expect to see its onset within a four week time frame of a preceding bacterial infection. Although the Court does not opine on whether Still's disease is a type of Reactive Arthritis, as described in Respondent's Exhibit I, it does note that Richie had diarrhea within four to five weeks preceding the onset of her Still's disease. Pet. Ex. 3 at 15.

FN43. "A type of small bacteria, which lack the rigid cell walls common to most bacteria. A causative agent of pneumonia in humans and some domestic animals is Mycoplasma pneumonia. Various species are troublesome contaminants of animal cell cultures, in which they may grow attached or close to cell surfaces, subtly altering properties of the cells, but escaping detection unless specifically monitored. One hypothesis is that mycoplasma are capable of causing otherwise unexplained symptoms in humans." www.gulflink.osd.mil/medsearch/glossary/glossary_m.shtml. See also note 13 supra.

could have caused Richie's "tonsillitis that she had about two weeks before the immunization, which had then resolved at the time of the immunization." *Id.*; Pet. Ex. 3 at 11-12. Dr. Rose testified that the antibody for mycoplasma "rises about three weeks from the infection and it lasts approximately a month, month and a half." *Id.* at 464. Such timing would place any infection causing the production of the mycoplasma antibody around or prior to Richie's vaccination date.

Dr. Levin testified that mycoplasma infections have been known to cause autoimmune diseases. *Id.* at 212. However, Dr. Levin stated that he was "not aware of mycoplasma causing Still's disease." *Id.* Dr. Levin went on to state that "[w]hether the mycoplasma contributed to her [Still's disease] or not, I don't have an opinion, but even if the mycoplasma did, it wouldn't have taken away the causal element of the vaccination." *Id.* "[T]here's no question that she had a reaction to the injections, because that was identified by swelling and inflammation around the injection site. Then she developed the rash, which is certainly not consistent with mycoplasma, and then she developed the arthropathy." *Id.* Respondent has put forth no argument that the mycoplasma was the cause of Richie's Still's disease.

Dr. Berger testified that x-rays of Richie's sinus cavity, taken on 13 April 2004, showed a "thickening of the sinus membranes ... that could be compatible with a sinus infection." Trans. at 365; Pet. Ex. 4 at 83. Dr. Berger added that "[i]t certainly was not a finding of severe" sinus infection. *Id.* Dr. Rose testified that the sinus infection or the earlier bout with tonsillitis could have been the cause of the cytokine production. *Id.* at 464. However, neither expert put forth any explanation why these alternative causes were more likely than the vaccinations at issue to have caused Richie's Still's disease. [FN44]

FN44. Of course a respondent does not have the burden to prove a factor unrelated to the vaccination was the cause of injury unless and until the petitioner establishes a prima facie case under the Vaccine Act. See *Flores*

(continued...)

(D) The Court's summation of its findings.

Articulating an objective analysis for causation in fact is akin to an elusive wraith. As Dean Prosser and the editors of a Torts hornbook have put it:

There is perhaps nothing in the entire field of law which has called forth more disagreement, or which the opinions are in such a welter of confusion. Nor, despite the manifold attempts which have been made to clarify the subject, is there yet any general agreement as to the best approach. [FN45]

This Court, as set out in this and numerous past decisions, makes two queries: (1) Can the vaccine(s) cause the injury alleged; and, (2) Did the vaccine(s) cause the injury alleged in this case? Although the theory put forth by Dr. Levin is novel, the Court, as stated supra, finds that it is biologically plausible and meets the preponderance of the evidence burden in answering the question "can it."

Answering the question "did it" in this case has presented the Court with considerable consternation. The Court has painstakingly looked for the feather in Petitioners' argument that would tip the scales past the fifty percent threshold. Ruefully, the Court's search was unsuccessful.

The link missing from Petitioners' argument that gave this Court pause was the lack of any defined time period in which one would expect to see the onset of Still's disease subsequent to a triggering event. Without such a defined time period, the link between the vaccinations and the injury is tenuous. This Court has always held that vaccines are not the cause of every event that occurs soon after their administration. [FN46] Additionally, the medical records indicate within the one month prior to the onset of her injuries, Richie suffered

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v. Sec'y Health and Human Services, 52 Fed. Cl. 294 (2002).

FN45. PROSSER AND KEETON ON TORTS, 5TH EDITION 263 (1984).

FN46. *Hasler v. United States* , 718 F.2d 202, 205 (6th Cir.1993), cert. denied, 469 U.S. 817 (1994).

from a cold and diarrhea, Pet. Ex. 3 at 15, inflamed tonsils with white patches on them and a fever of 101-102 degrees Fahrenheit. *Id.* at 13- 15. Although the Court does not definitively find that one of these triggered the onset of her Still's disease, the point is that the vaccinations at issue were not the only contemporaneous events. In the end, the Court finds that Petitioners' argument amounts to nothing more than a post hoc ergo propter hoc assertion. This is not enough to meet their burden. See *Fricano v. United States*, 22 Cl.Ct. 76, 80 (1991) ("post hoc ergo propter hoc ... is regarded as neither good logic nor good law."). [FN47]

Whenever the Court decides the merits of a novel medical theory, as is the case here, it runs the risk that such theory, over time, may eventually prove correct. However, the Court can only opine based upon the evidence available.

The Court finds that Petitioners have not met their burden of proof that by a preponderance of the evidence the 24 March 1998 vaccinations caused Richie's Still's disease. Accordingly, compensation must be denied.

V. CONCLUSION

This petition is DISMISSED with prejudice, pursuant to Vaccine Rule 21, for failure to prove a prima facie case for entitlement under the Vaccine Act. In the absence of a motion for review filed pursuant to RCFC, Appendix B, the clerk is directed to enter judgment accordingly.

IT IS SO ORDERED.

FEDCLSPMAS,2004.

Pafford v. Secretary of Dept. of Health and Human Services 2004 WL 1717359 (Fed.Cl.)

FN47. "[A] showing of biologic plausibility and temporal association is insufficient...." *Huston v. Sec'y of Health and Human Services*, 39 Fed. Cl. 632 (1997).

Appendix B

64 Fed.Cl. 19

United States Court of Federal Claims,

LISA ANN PAFFORD AND RICHARD LEON PAFFORD PARENTS AND NEXT FRIENDS OF RICHELLE LORRAE PAFFORD, a minor,	)	
Petitioners,	)	
v.	)	No. 01-0165V
SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,	)	
Respondent.	)	

Filed Under Seal: Jan. 25, 2005. Reissued: Feb. 9, 2005. [FN1]

Robert T. Moxley, Cheyenne, Wyoming, for petitioners. Melonie J. McCall, United States Department of Justice, Washington, DC, for respondent.

I. Introduction

This case is before the court under the National Childhood

FN1. This opinion originally was issued under seal on January 25, 2005. The court afforded the parties an opportunity to propose redactions in the opinion prior to its publication, but no such redactions were proposed. Accordingly, the opinion is herein reissued for publication, unsealed.

Vaccine Injury Act [FN2] for review of the Special Master's decision to deny petitioners' claim for compensation. Young Richelle Pafford was diagnosed with systemic onset Juvenile Rheumatoid Arthritis ("JRA"), also known as Still's disease. Richelle's condition is made all the more painful by the inability of modem medical science, especially given all of its recent spectacular advances, to understand the exact mechanism of the origin of JRA.

Under the guise of the great sleuth Sherlock Holmes, Sir Arthur Conan Doyle once posited that "when you have eliminated the impossible, whatever remains, however improbable, must be the truth." [FN3] Because of science's failure to here provide a concrete answer (a dispositive etiology for JRA is unknown), the fundamental issue in this case essentially involves the application of Holmes' maxim of deductive reasoning to the law-what Dr. Watson surely should have recognized as a specie of differential diagnosis-in an effort to determine the cause of Richelle's illness. Consequently, the dilemma petitioners face here is whether the quantum of proof they proffered ascertaining causation-in-fact rises to the level of legal sufficiency. Indeed, as discussed below, it is this very question of legal sufficiency of the proof of causation-which is at the very heart of this case-that has vexed both the Special Masters and the reviewing courts since the inception of the Act.

After a hearing held July 7-8, 2003, the Special Master concluded that petitioners did not meet their burden of demonstrating legal causation-in-fact under the Act. More particularly, the Special Master found that while petitioners had demonstrated that vaccine reactions hypothetically could trigger systemic onset JRA similar to Richelle's, petitioners failed to satisfy the burden of proof that Richelle's condition

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FN2. Public Health Services Act, § 2111(b)(1)(A) (codified as amended at 42 U.S.C. §§ 300aa-1 to -34).

FN3. Arthur Conan Doyle, The Sign of Four, ch. 6 (1890) (original emphasis omitted).

in this specific case was in fact triggered by a vaccine. *Pafford v. Sec'y of the Dep't of Health and Human Servs.*, No. 01-0165V, 2004 WL 1717359 (Sp.Mstr.Fed.Cl. July 16, 2004). The predicate for this determination was the failure of petitioners to produce any evidence (1) showing that Still's disease would manifest within a particular period of time following the triggering event or (2) discounting the causative role of other ailments that coincided with Richelle's vaccination. *Id.* On August 16, 2004, the petitioners filed a Motion for Review of the Special Master's decision in this court, seeking to overturn the denial of compensation, essentially arguing that the Special Master applied the wrong standard of legal causation-in-fact.

Upon review of the Special Master's opinion and the entire record, and for the reasons addressed more thoroughly below, the court concludes that the Special Master has satisfied the applicable legal standard in finding that the petitioners did not meet their statutory burden of proving Richelle's March 1998 vaccination was the cause-in-fact of Richelle's subsequent systemic onset JRA.

II. Background[FN4]

Richelle Pafford was born January 30, 1993. She received regular medical care from Dr. Jay Schmidt, and the Special Master noted "nothing remarkable" about Richelle's early development. On August 5, 1993, when Richelle was just more than six months old, Dr. Schmidt administered her first DTP, OPV and Hib vaccinations.[FN5] The second series of

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FN4. The court does not ordinarily make independent findings of fact in these cases, but rather reviews the findings of the Special Master. Accordingly, the factual background that follows is primarily taken from the Special Master's decision.

FN5. The DTP vaccine protects against diptheria, pertussis (whooping cough), and tetanus; the DTaP vaccine, which Richelle received later, is the same as the DTP but contains an acellular pertussis vaccine and is recommended for children at 18 months and 4-6 years. The OPV is an oral polio vaccine, and the Hib immunization helps prevent diseases caused by

(continued...)

these vaccinations followed eleven weeks later, on October 21, 1993. Nearly seven months later, on May 10, 1994, Dr. Schmidt administered Richelle's third DTP, OPV and Hib vaccinations and her first MMR [FN6] vaccination. During an examination on the same day, Dr. Schmidt noted normal development. Seventeen days later, on May 27, 1994, Richelle developed a faint rash on her face, legs and arms that lasted five days. When she visited Dr. Schmidt on June 1, he noted that Richelle's tonsils were "inordinately enlarged [and] red;" a subsequent strep throat culture was negative. Pet.'s Ex. 3 at 44-45. Dr. Schmidt also noted that Richelle's mother had recently experienced a flu-like illness that was followed by a rash. *Id.* at 44.

During November and December 1997, when Richelle was almost four years old, she was treated for otitis, an inflammation of the ear marked by pain, fever, hearing difficulty and vertigo. Dr. Schmidt noted that she complained of a cold lasting two months. Pet.'s Ex. 3 at 20. Three months later, on March 5, 1998 Richelle visited Dr. Schmidt with complaints of a cold and diarrhea that had lasted about three days. One week later, on March 12, Richelle returned to Dr. Schmidt with inflamed tonsils bearing white patches. She also ran a fever of 101-102 degrees Fahrenheit. Dr. Schmidt diagnosed Richelle with tonsillitis and conducted another throat culture that was negative for strep throat. Pet.'s Ex. 3 at 13-15. On March 24, Richelle returned for a follow-up visit, during which Dr. Schmidt noted that her tonsils were no longer inflamed and had regressed in size from the recent exam. *Id.* at 11. Richelle was noted to be "doing well" and was "suffering no symptoms of illness;" she was an active child with healthy physical and mental development. *Id.* During

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(...continued)

Haemophilus influenzae type B, including meningitis. See http://www.medterms.com.

FN6. The MMR immunization is the standard vaccine given to prevent measles, mumps and rubella (German measles). *Id.*

this March 24 visit, Richelle received a DTaP vaccination, her fourth OPV vaccination, and her second MMR vaccination. It is this series of vaccinations (the March 1998 vaccinations) that petitioners have placed at issue in this case.

Eleven days later, on April 4, 1998, Richelle complained of fever and neck pain. Her fever abated the next day, but her neck pain persisted. She developed a diffuse pink, macular rash and whitish spots on her tongue that may have been Koplik's spots [FN7] and also complained of limb pain. On April 7 Richelle returned to Dr. Schmidt for evaluation. She was then diagnosed with a vaccine-induced rash and instructed to avoid contact with others for five days.

Six days later, on April 13, Richelle was treated at the emergency room in United Medical Center, Cheyenne, Wyoming; she had a 103.9 degree fever and a blanching red maculopapular rash on the palms and soles of her hands, upper legs, chest and upper abdominal area. She was vomiting upon arrival and refused intake of fluids. The consulting physician, Dr. Valerie Bell, noted that Richelle was tearful and crying, and Dr. Bell "could not localize any tenderness specifically because she cried everywhere she was touched." Pet.'s Ex. 5 at 16. Dr. Bell also noted that "[t]he rash was very viral in character and I did not feel it was related to her immunizations but suggested a [complete blood count] to see if it supported the viral picture." *Id.* By the time that Richelle was admitted to the hospital floor from the emergency room, her fever had abated to 97.2 degrees and the rash "had greatly diminished by that time." *Id.* at 8. She was by then "playful and happy." *Id.* at 16. Dr. Schmidt noted that the "fever and rash abated quite remarkably and rapidly" and he sensed that the rash was related to the fever. *Id.* at 8-9. At this time, Richelle also tested positive for a mycoplasma

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FN7. Koplik's Spots are "small, irregular, bright red spots on the buccal and lingual mucosa, with a minute blueish white speck in the center of each; seen in the prodromal stage of Measles." Dorland's Illustrated Medical Dictionary 971 (27th ed.1988). Koplik's Spots are often, if not always, a definitive symptom of Measles.

infection, and Dr. Bell thought that this was responsible for the April 13 symptoms. See Pet.'s Ex. 4 at 79. Upon discharge, Richelle was afebrile and "her rash, for the most part, had disappeared." Pet.'s Ex. 5 at 9.

After she had gone home, Richelle experienced recurring fever and rash over the next two weeks and increasingly complained of joint pain. On April 30, 1998 she returned to Dr. Bell, who noted that Richelle had a 102.9 degree fever, a painful, swollen right elbow and left knee, and a recurrence of the earlier rash. While Dr. Bell had previously thought that Richelle's rash, joint pain and fever "were all due to mycoplasma," by this point it "seem[ed] the illness has extended longer than would be expected with mycoplasma." Pet.'s Ex. 4 at 79. Although Dr. Bell noted that the joint discomfort associated with mycoplasma can last for weeks, the rash and fever do not usually relapse to the extent that Richelle experienced. *Id.* at 80. Instead, Dr. Bell "strongly suspect[ed] systemic onset JRA as the cause of the month long recurrent rash, fever and discomfort." *Id.* Richelle's lab results revealed an elevated sedimentation rate of 80, mild anemia, and negative ANA and rheumatoid factor tests.

Richelle subsequently embarked on a medication regime to treat her JRA. Dr. Bell's diagnosis was later corroborated by Dr. Hollister, a pediatric rheumatologist at Children's Hospital in Denver, Colorado. Despite treatment, Richelle's disease remained active with recurrent arthritis through at least the next two years.

In 2001 Richelle's parents filed a petition for compensation under the Vaccine Act. It was their theory that Richelle's JRA was caused by her adverse reactions to the vaccines that she received in March 1998. The Special Master who reviewed Richelle's case conducted a two-day hearing with both parties' experts, and filed a decision denying compensation to the Paffords on July 16, 2004. *Pafford*, No. 01-0165V, 2004 WL 1717359 (Sp.Mstr.Fed.Cl. July 16, 2004).

III. The Vaccine Act

The Vaccine Act provides a program by which individuals who claim to have been injured by certain vaccines may be

compensated for their injury. The program was created in large part to preempt tort litigation against vaccine manufacturers and provide compensation to injured individuals without requiring the rigorous burdens of proof associated with products liability litigation, including causation, negligence, and product defectiveness. See generally *Stevens v. Sec'y of the Dep't of Health and Human Servs.*, No. 99-594V, 2001 WL 387418 at *6 (Sp.Mstr.Fed.Cl. Mar. 30, 2001). Instead, a petitioner under the Act may circumvent proof of causation by relying on the "Vaccine Injury Table." See 42 U.S.C. § 300aa-14(a). If the petitioner's injury is "on-Table" then the Act establishes a presumption that the vaccine caused the injury if the petitioner demonstrates that the onset or "significant aggravation" of predicate injuries occurred within a statutorily prescribed time period. See § 300aa-11(c)(1)(C)(i); *Bunting v. Sec'y of the Dep't of Health and Human Servs.* , 931 F.2d 867, 872 (Fed.Cir.1991). If the petitioner establishes the presence of an on-Table injury, then the Act authorizes compensation so long as the presumption is not rebutted by "a preponderance of the evidence that the ··· injury ··· is due to factors unrelated to the administration of the vaccine." § 300aa-13(a)(1)(B); see also *Grant v. Sec'y of the Dep't of Health and Human Servs.*, 956 F.2d 1144, 1146-47 (Fed.Cir.1992).

On the other hand, if the claimed injury is not an on-Table injury-as is the case here with Richelle's systemic onset JRA-then the petitioners may still seek compensation provided they are able to prove causation-in-fact. § 300aa-11(c)(1)(C)(ii); *Grant*, 956 F.2d at 1147. A petitioner's path to compensation for an "off-Table" injury is considerably more tortuous because the petitioner does not benefit from the presumption of causation that attaches to an on-Table case. Instead, the petitioner must demonstrate by a preponderance of the evidence that the vaccination in question, more likely than not, was in fact the cause of the alleged injury. *Grant*, 956 F.2d at 1147-48. Unlike an on-Table case, proof of causation in an off-Table case must comprise more than just a literal temporal association

between the onset of the injury and the vaccination. "When a petitioner relies upon proof of causation in fact rather than proof of a Table Injury, a proximate temporal association alone does not suffice to show a causal link between the vaccination and the injury." *Id.* at 1148. As part of the burden of proof, a petitioner must present "a medical theory causally connecting the vaccination and the injury." *Id.* (citing *Hasler v. United States*, 718 F.2d 202, 205-06 (6th Cir.1983)). Furthermore, this causal connection must be supported by "reputable medical or scientific explanation." *Id.*; 42 U.S.C. § 300aa-13(a)(1). Finally, according to Federal Circuit precedent, the petitioner bears the burden of proving that "the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury." *Shyface v. Sec'y of the Dep't of Health and Human Servs.*, 165 F.3d 1344, 1352-53 (Fed.Cir.1999). Ultimately, as discussed at length below, it is this "but-for" standard where petitioners here fall short.

IV. The Special Master's Decision

As an initial matter, the Special Master endeavored to clarify just what systemic onset JRA, or Still's disease, is. See *Pafford*, No. 01-0165V at 5-6, 2004 WL 1717359 (Sp.Mst.Fed.Cl. July 16, 2004). A type of juvenile rheumatoid arthritis, it typically begins with symptoms of a systemic (body wide) illness including high fever "spikes," gland swelling and internal organ involvement that all coincide with joint inflammation. "Extreme fatigue can accompany waves of high fevers that rise daily ··· and rapidly return to normal levels···· A faint salmon-colored skin rash characteristically comes and goes and does not itch. Arthritis, with joint swelling, often occurs after rash and fevers have been present for some time." *Id.* at 6. In children, Still's disease inflames large joints and may retard bone growth. As to the culprit that causes Still's disease, "[a] dispositive etiology is unknown, but like many other types of arthritis, abnormal immune response, genetic predisposition and environmental triggers, and infectious agents are all being considered." *Id.*

The Special Master then proceeded to evaluate petitioners' causation-in-fact claim. Citing *Grant*, the court organized the legal criteria of the causation-in-fact analysis into two overriding considerations. " First, a petitioner must provide a reputable medical theory causally connecting the vaccination and the injury···· Second, a petitioner must also prove that the vaccine actually caused the alleged symptoms in her particular case." *Id.* at 7. The first prong of this evaluation was distilled to concentrate on the "biologic plausibility" of the petitioners' theory "by proffering a scientific pathogenesis underlying the alleged causal relationship." *Id.* Generally, the Special Master noted, biologic plausibility is established through epidemiological studies, peer-reviewed published articles in medical journals, and acceptance of theories in at least a subset of the medical community. If biologic plausibility is established, then the second prong of the Special Master's causation-in-fact analysis turns to whether the petitioner has proved whether her case is consistent with the mechanism or model presented, i.e. whether the petitioner has explained "how and why the injury occurred" in that particular instance. *Id.* at 8. Furthermore-and this was key to the Special Master's decision-"[r]uling out other potential causes is an essential element [of the plausibility causation-in-fact analysis] but does not itself establish causation." *Id.* In other words, the Special Master determined that elimination of alternative causes of Richelle's Still's disease (other than the vaccines) was a necessary, but not sufficient, element of the petitioners' case.

Ultimately, this two-pronged approach was tailored as "(I) Is it biologically plausible that one or more of the vaccinations in question can cause Still's disease?; and, (ii) Did one or more of [Richelle's] vaccinations result in her Still's disease?" *Id.* As to the initial prong, the court concluded that petitioners had proven by a preponderance of the evidence that it is indeed biologically plausible for one or more of the vaccinations at issue to cause the onset of Still's disease. *Id.* at 9. Generally, both parties' experts agreed that certain

individuals have a genetic predisposition to Still's disease. One of the hallmarks of the disease, according to these experts, is an increase in the expression of pro-inflammatory cytokines, [FN8]which fuel the symptoms of Still's disease. Respondent's expert, Dr. Berger, noted that it is the excessive and prolonged cytokine production that results in the manifestation of the disease. *Id.* Indeed, one of the highly successful treatments for Still's disease involves reducing the level of certain cytokines in the body. However, unfortunately for those with a genetic predisposition to the disease, and as agreed by the experts in this case, vaccines induce cytokine production. *Id.* "Cytokines are produced by the host after receiving the vaccination. If vaccines could not induce cytokines, they could not induce immunity for you to protect against the infectious agent." *Id.* (quoting respondent's expert, Dr. Rosé). Ostensibly, the body's natural expression of cytokines following a vaccination is misregulated in individuals predisposed to Still's disease, and the over-expression of those cytokines results in the manifestation of the actual condition.

Having concluded that petitioners carried their burden for the first prong, the Special Master then evaluated their effort to prove that Richelle's systemic onset JRA was in fact an autoimmune response triggered by the over-production of cytokines specifically induced by her March 1998 vaccinations, consistent with petitioners' proffered mechanism. The court concluded that there was ample evidence of a literal temporal relationship between the vaccinations and Richelle's subsequent symptomatic expression of Still's disease. She seemed to demonstrate "typical post-vaccinal side effects" from the MMR vaccine in early April, eleven days after the vaccination. *Id.* at 11-12. Through the first week in April 1998, her symptoms appeared

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FN8. "A generic term for non-antibody proteins released by one cell population on contact with a specific antigen, which act as intercellular mediators, as in the generation of an immune response." Dorland's at 427-28.

to be ordinary side effects of the vaccine, including fever, neck pain, rash and fatigue. [FN9] According to the Special Master, "[t]he onset of [Richelle's] Still's disease is apparent some time during the second week of April 2004," or about three weeks after the vaccination. *Id.* at 12. It was by that point that she demonstrated the spiking fever accompanied by a transient and recurring rash. Furthermore, during the final weeks of April, Richelle complained of joint pain. These symptoms were consistent more with Still's disease than a reaction to the vaccines (or the mycoplasma, as Dr. Bell had earlier suspected), and the doctors concluded by late April, just one month after the vaccination, that Richelle was indeed suffering from Still's disease.

The petitioners argued that the onset of Still's disease within just a few weeks of the March 1998 vaccinations was strong evidence suggesting a causal connection between the two. The Special Master, however, refused to place such great weight on this mere literal temporal relationship, noting that such "is not itself sufficient for Petitioners to meet this Court's burden of proof by a preponderance of the evidence." *Id.* at 13. Since the petitioners in this case seemed to rely solely on the temporal relationship between alleged cause and ultimate effect, the Special Master noted that the one instance in which such temporal evidence is "telling" in a causation-in-fact case is where the manifestation of the claimed injury "falls within an established time period subsequent to an antecedent or triggering event." *Id.*

FN9. "As with other vaccines, MMR can cause a local reaction with pain and induration at the injection site. Because it is a live virus vaccine, mild illness with symptoms similar to measles, mumps or rubella may occur. About 7-12 days after vaccination, five percent of children develop a fever with temperature greater than 103 degrees, which lasts 1-2 days. A transient rash may occur 7-10 days post vaccination in 5 percent of children (due to the measles and rubella components). Transient lymphadenopathy (rubella component) and rare parotitis (mumps component) have also been described." Pafford, No. 01-0165V at 11-12 n. 37, 2004 WL 1717359 (quoting http:// www.corexcel.com/courses/body.immunizations.page9.htm) (citations omitted).

However, petitioners failed to demonstrate that Still's disease necessarily, or at least routinely, manifests symptoms within any certain timeframe following a given triggering event. *Id.* Therefore, the literal temporal relationship alone was not dispositive: "The link missing from Petitioners' argument that gave this Court pause was the lack of any defined time period in which one would expect to see the onset of Still's disease subsequent to a triggering event. Without such a defined time period, the link between the vaccinations and the injury is tenuous." *Id.* at 15

Additionally, the Special Master noted that "[a]ll experts agree that a number of things can trigger Still's disease." *Id.* at 14. In Richelle's case, along with the March 1998 vaccinations there was evidence of concurrent events, including an ear infection, tonsillitis and the high mycoplasma count, that might have potentially triggered the manifestation of Still's disease instead of the vaccinations.[FN10] Although respondent did not point to any one of these potential alternative causes as a specific triggering event, respondent's experts tended to suggest that either an infection or tonsillitis could trigger an autoimmune response that resulted in Richelle's Still's disease, consistent with petitioner's proffered mechanism. *Id.* Ultimately, the Special Master concluded that although it was not clear at all that one of these potential alternatives in fact caused

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FN10. See Hearing Transcript, filed Aug. 8, 2003, at 171 ("[A]utoimmune disease ··· [is] an immune mediated inflammatory disorder. It's a disregulation of certain proinflammatory cells and ··· these cells tend to be triggered by something···· [T]hey could be triggered by ··· toxic chemicals, viral infections, vaccines ··· you name it.") (Testimony of Dr. Levin), 174-75, 212 (Q: "You would agree, Doctor, that mycoplasma infections have been known to cause other autoimmune diseases, correct?" A: "Yes") (Testimony of Dr. Levin), 363-65, 436, 460-65 (Q: "You mentioned in your expert report that cytokines can be produced by smoke inhalation, cancer, things like that. You can't identify any of those factors in Richelle Pafford's case, can you?" A: "Well, what about the eight to twelve infections a year? The tonsillitis that she got in March? Is it not there? How about the sinus infection; how [about] the IGM form with mycoplasma?").

Richelle's Still's disease, "the point is that the vaccinations at issue were not the only contemporaneous events." Implicitly, then, the Special Master seemed to weigh against petitioners the fact that they had not discounted the role of viable alternative causes in Richelle's case. Ultimately, the Special Master's concerns about (a) the absence of evidence of a defined temporal relationship between a triggering event and the manifestation of Still's disease symptoms and (b) the petitioners' failure to discount possible alternative causes of Richelle's condition led him to conclude that petitioners were not entitled to compensation.

Petitioners then filed in this court a motion for review of the Special Master's decision, generally raising two lines of arguments focusing on the "critical time" element and the alternative causation theory that were the lynchpins of the decision. First, they argue that the Special Master's opinion was legally flawed because he misinterpreted the appropriate standard of proof that applies when a petitioner introduces evidence of a temporal relationship between alleged cause and effect in a causation-in-fact case. They argue that in this case there was ample evidence that indicates a definite time period in which the medical community would expect a patient to demonstrate symptoms of a reaction to a vaccine, and that Richelle's vaccine reactions did in fact occur within those periods. Accordingly, the Special Master's failure to consider this evidence, petitioners argue, was arbitrary and capricious. Furthermore, they claim that the Special Master abused his discretion by raising the issue of "critical time" sua sponte after the hearing when neither party had raised any question with regard to the timing of Richelle's Still's disease. Second, petitioners claim that it was legal error for the Special Master to attribute the burden of proof as to potential alternative causes of Richelle's condition to them and not respondent.

V. Discussion

At its heart, then, petitioners' contentions in this court focus squarely on the appropriate standard of proof to which a petitioner should be held in an off-Table Vaccine Program

causation-in-fact case. It raises issues regarding both a petitioner's burden of production, i.e. the types of evidence the petitioner must demonstrate to establish a prima facie entitlement to compensation, as well as the burden of persuasion, i.e. the degree to which the petitioner must persuade the fact-finder.

A. Jurisdiction And Standard Of Review

Pursuant to 42 U.S.C. § 300aa-12(e), this court may review the Special Master's decision upon motion by the parties. The court, in turn, may (a) uphold the findings of fact and conclusions of law of the Special Master and sustain the decision, (b) set aside any finding of fact or conclusion of law that is arbitrary, capricious, or an abuse of discretion, or (c) remand the petition to the Special Master for further action. See § 300aa-12(e)(2). These standards, however, vary in application as well as in degree of deference. Under the Act, this court reviews findings of fact according to the "arbitrary and capricious standard," focusing on whether the Special Master examined the relevant data and articulated a "satisfactory explanation for [his] action including a rational connection between the facts found and the choice made." *Dixon v. Sec'y of the Dep't of Health and Human Servs.*, 61 Fed.Cl. 1, 8 (2004) (quoting *Motor Vehicle Mfrs. Assn. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43, 103 S.Ct. 2856, 77 L.Ed.2d 443 (1983)). The arbitrary and capricious standard of review accorded to the Special Master's decision by statute is highly deferential. "If the special master has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision, reversible error will be extremely difficult to demonstrate." *Hines v. Secretary of Sec'y of the Dep't of Health and Human Servs.*, 940 F.2d 1518, 1528 (Fed.Cir.1991). Legal questions, on the other hand, are reviewed under the less deferential "not in accordance with law" standard. Discretionary rulings are reviewed for an abuse of discretion. *Saunders v. Sec'y of the Dep't of Health and Human Servs* ., 25 F.3d 1031, 1034 (Fed.Cir.1994).

B. The Standard Of Proof In Causation-In-Fact Cases

"There is a dearth of precedent discussing the requirements for prima facie causation." *Shyface*, 165 F.3d at 1350. It has been noted that petitioners in off-Table Vaccine cases tend to rely on similar types of evidence in proving their claims. See generally *Stevens*,[FN11] 2001 WL 387418 at *12 ("For the most part, petitioners submit the same type of evidence in almost every vaccine claim."). Traditionally, it appears to this court that petitioners often, if not always, choose one of two paths in their journey to establish causation-in-fact in off-Table cases. For convenience, these two paths may be thought of as the direct causation argument and the plausibility argument. The type of case that a petitioner should mount is entirely dependant upon the type of evidence able to be produced.

Despite *Althen's* treatment of *Stevens*, this court notes that *Stevens* does take considerable care to explain the Vaccine Act and the manner by which petitioners routinely try to establish causation-in-fact. See *id.* at *9-23. The court finds *Stevens'* thorough review and discussion of the state of Vaccine Program causation-in-fact jurisprudence extremely useful as an analytic tool and a starting point for analysis.

1. Direct Causation

If and when a petitioner has scientific or medical evidence that demonstrates a direct causal relationship between the vaccine and the injury, then proof of causation-in-fact via direct causation is the preferred path. "[S]pecial masters

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FN11. The Stevens decision has come under some scrutiny by this court, see *Althen v. Sec'y of the Dep't of Health and Human Servs* ., 58 Fed.Cl. 270 (2003), for the five-step analytic framework that the Chief Special Master promulgated. In *Stevens* the Chief Special Master indicated that a petitioner satisfies the prima facie burden of demonstrating causation-in-fact by a preponderance of the evidence if he demonstrates proof of each of the following: (1) medical plausibility; (2) confirmation of medical plausibility from the medical community and literature; (3) an injury recognized by the medical plausibility evidence and literature; (4) a medically acceptable temporal relationship between the vaccination and the onset of the alleged injury; and (5) the elimination of other causes. See *Stevens*, 2001 WL 387418 at *23-26.

initially look for direct evidence linking the vaccine to the alleged injury." *Id.* Evidence of direct causation may be found in the form of "an epidemiologic study demonstrating a relative risk greater than two ··· or dispositive clinical or pathological markers evidencing a direct causal relationship."[FN12] *Id.* Although the minimum legal burden of persuasion required in causation-in-fact cases is only a preponderance of the evidence and "not scientific certainty," see *Bunting,* 931 F.2d at 873, direct evidence tends to move the physician and fact-finder towards the "scientifically certain" end of the spectrum of proof, which far exceeds a mere preponderance legal standard. Logically, the presence of direct evidence establishing a causal link between vaccine and injury obviates the need for an analysis of biologic plausibility because direct proof that the vaccine did in fact cause the injury necessarily means that it could have done so. Similarly, given the strong causal relationship established by evidence of direct causation, petitioners do not need to also rely on circumstantial factors that are often implicated in a plausibility argument, discussed below. For example, the need to prove a medically accepted time frame for the onset of injuries or to discount the presence of alternative causes present in the record-which were both implicated in the Special Master's opinion here-is subsumed by the highly probative direct evidence.

Unfortunately for most petitioners, epidemiologic studies, dispositive clinical markers or pathological "footprints" are not often available. Epidemiologic studies may be unavailable because "relevant research regarding causation is often extremely limited. A number of factors restrict the medical community's efforts to conduct such studies including the costliness of the research and the rarity of the illnesses studied." *Id.* at *14. Clinical markers may be absent because

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FN12. "[F]or example, the presence of anterior horn cells on autopsy as evidence of polio contracted from the oral polio vaccine or the presence of the rubella virus in synovial fluid taken from the joints as evidence of a rubella-related arthropathy." *Stevens,* 2001 WL 387418 at *12.

certain tests were not conducted at the time of sickness or because science has not yet identified acceptable markers. *Id.* Indeed, in this case petitioners could not present direct evidence supporting the theory of one of its experts because at the time "nobody looked" for the markers that might have supported that theory, i.e., potentially supportive tests were not conducted.[FN13] Similarly, petitioners were unable to produce evidence that Richelle had higher levels of cytokine expression because, at the time of onset, the medical field had yet to develop testing sophisticated enough to identify specific cytokines.[FN14] An inability to generate direct evidence of causation forces a petitioner to instead try and prove causation-in-fact using circumstantial evidence as part of a plausibility argument.

2. Plausibility

"With few exceptions, the special masters encounter the absence of dispositive epidemiology or vaccine footprints in the vast majority of causation-in-fact cases under the [Vaccine] Program." *Id.* In those cases, the petitioner is forced to make his argument employing circumstantial evidence that helps meet the preponderance standard. Such circumstantial evidence may include: epidemiology (evidencing a relative risk less than two), animal studies, case reports/case series studies, anecdotal reports, manufacturing disclosures, Physician Desk Reference citations, journal articles,

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FN13. Specifically, petitioner's expert Dr. Geier opined that the rubella virus contained in the MMR vaccine can produce chronic infection in synovial tissue resulting in the onset of JRA. Dr. Geier stated that direct proof of that infection would be the presence of the rubella virus in the synovial fluid, but the rubella virus was not isolated in any of Richelle's synovial fluid because those tests were not conducted. See *Pafford*, No. 01-0165V at 2 n. 2, 2004 WL 1717359.

FN14. The Special Master did note, however, that indirect tests revealing a high white blood cell count, which were conducted by Richelle's doctors, correlate with a high cytokine count because white blood cells secrete cytokines. Therefore, a high white blood cell may indicate a corresponding increase in cytokine expression.

institutional findings (such as those reported by the Institute of Medicine), novel medical theories, treating physician testimony, and non-dispositive but inferential clinical and laboratory findings.

Id. The speculative nature of proving causation-in-fact in Vaccine cases with circumstantial evidence requires the petitioner to do much more of the "heavy lifting" than in an on-Table case or even in an off-Table case where there is direct evidence. See *Lampe v. Sec'y of the Dep't of Health and Human Servs.*, 219 F.3d 1357, 1360 (Fed.Cir.2000); *Hodges v. Sec'y of the Dep't of Health and Human Servs.*, 9 F.3d 958, 961 (Fed.Cir.1993). First, as the Special Master here proceeded, the petitioner must establish that the vaccine could possibly cause the claimed condition. The need for this initial analysis of biologic plausibility is obvious: in evaluating whether the vaccine was more likely than not the cause of a condition, we must first know if it was even possible for the vaccine to have such an effect. If the petitioner's proffered mechanism is beyond the realm of plausibility, then any other circumstantial evidence that remains, no matter how persuasive, cannot overcome the petitioner's initial fallacy.

Once biologic plausibility has been established, as it was in this case, the petitioner must demonstrate some nexus between the mechanism and the actual condition that shows, more likely than not, that the vaccine caused the condition. See, e.g., *Munn v. Sec'y of the Dep't of Health and Human Servs.*, 970 F.2d 863, 867 (Fed.Cir.1992) (affirming Special Master's decision that petitioner "failed to establish a nexus" between the vaccine and injury). As *Stevens* illustrates, though, it is not clear just what suffices for this "nexus":

[C]onflict also surrounds what amount or combination of evidence sufficiently demonstrates causation generally and in the particular case. Some cases consider the combination of a demonstrated mechanism or medical plausibility and a temporal relationship insufficient···· Others consider the combination of medical plausibility (an accepted or plausible medical theory) and the elimination of alternate causes

satisfactory. Some cases suggest plausibility, a medically appropriate temporal relationship, and the elimination of alternate causes suffices to prove causation.
Id. at *20 (citations omitted).
With regard to the temporal relationship between vaccination and the onset of a subsequent condition, there is a distinction drawn between what some courts refer to as the "literal temporal relationship" and a more refined "scientific temporal relationship." The former refers merely to the period of time between the vaccination and the onset of symptoms; it is a mechanical approach. The latter, however, refers to a more analytic relationship in which the medical or scientific community recognizes a specific period of time following a vaccination within which a certain condition might materialize. See *Stevens*, 2001 WL 387418 at *2 n. 6 ("The term 'temporal relationship' has two possible meanings as used in litigation under the Vaccine Act: (1) the literal meaning, in other words, that the injury occurred subsequent to and close in time to the administration of the vaccine, or (2) the scientific meaning, in other words, that there is an accepted time frame supported by scientific evidence within which the injury should manifest itself following vaccination."). The Federal Circuit has indicated in *Grant* that a literal temporal association between vaccine and condition, alone, is not sufficient to establish causation-in-fact. See *Grant*, 956 F.2d at 1148. Instead, the petitioner must also demonstrate "a medical theory causally connecting the vaccination and the injury" and a "logical sequence of cause and effect showing that the vaccination was the reason for the injury." *Id.*
But these elements of causation-in-fact identified in *Grant* force a question that is key to the case at bar: if a petitioner demonstrates a plausible biologic mechanism and also shows a literal temporal relationship between the vaccination and the manifestation of a subsequent condition, has the petitioner satisfied his burdens? As petitioners contend, it would seem that such production would, at least facially, satisfy the limited requirements that *Grant* espouses.

To this court, however, the flaw in that argument is that the Federal Circuit has extended the analysis such that those minimum causation-in-fact elements enunciated in *Grant* may not be sufficient to establish a prima facie entitlement to compensation, depending on the unique circumstances of a given case. The Federal Circuit has instructed that an actual-causation vaccine petitioner "must prove by a preponderance of the evidence that the vaccine, and *not* some other agent, was the actual cause of the injury." *Munn*, 970 F.2d at 863 (emphasis added). This would seem to engender the need for a petitioner to eliminate other possible causes of the condition (other than the vaccine) that exist in the record. This deductive reasoning analysis has its origin in traditional tort law. Drawing parallels between the Restatement (Second) of Torts substantial factor standard in negligence cases and the vaccine cases, the Federal Circuit has indicated that "an action is the 'legal cause' of harm if that action is [both] a 'substantial factor' in bringing about the harm, and that the harm would not have occurred but for the action." *Shyface*, 165 F.3d at 1351-52 (citing Restatement (Second) of Torts §§ 431, 433) ("Some other event which is a contributing factor in producing the harm may have such a predominant effect in bringing it about as to make the effect of the actor's negligence insignificant and, therefore, to prevent it from being a substantial factor."). It is the petitioner who bears the burden of proving that the vaccine was both the "but for" cause as well as a "substantial factor" of the harm. *Id.* "Implementing this principle in terms of the Vaccine Act statutory provisions, establishment of prima facie entitlement to compensation according to the non-Table method would require the petitioner to prove, by a preponderance of the evidence, that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury." *Id.* To be sure, if the record indicates the existence of other possibilities as a reasonable culprit for the cause of the disease, it is very possible that the petitioner has not met either the "but for" or "substantial factor" requirement because those other possible culprits may well remain as

viable alternatives that undercut the vaccine's causative role. In other words, as a practical matter, in such a circumstance, petitioners must eliminate other reasonably possible causes that exist in the record to meet its burden of establishing a prima facie case for causation-in-fact.

Shyface and *Munn*, accordingly, seem to require the court to evaluate the record as a whole, and take into account whatever considerations that record may reveal, in determining whether the vaccine is the but-for cause and substantial factor of the subsequent condition. Consequently, if the record in a Vaccine case contains incidents that might put at issue whether the vaccine is a substantial factor contributing to the condition, even in light of the petitioner's demonstrated biologic mechanism and the literal temporal proximity between vaccine and condition, the Special Master may need to delve beyond the *Grant* requirements to establish causation-in-fact.[FN15] In light of the *Shyface* analysis, those minimum *Grant* requirements may become necessary, but not sufficient, elements of the analysis due to the entirety of the record.

This court therefore concludes that a Special Master does not act contrary to the law and commit reversible error if he determines that a plausible biologic mechanism and a literal temporal relationship, alone, do not establish such a nexus between vaccination and condition that causation-in-fact must obtain. See *Shyface*, 165 F.3d at 1351-52. A Special Master is well within his realm to demand that a petitioner demonstrate a degree of acceptable scientific support that goes beyond mere plausibility and temporal proximity, based on the given circumstances of the case before him. See

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FN15. See *Wagner v. Sec'y of the Dep't of Health and Human Servs.*, No. 90-2208V, 1997 WL 617035, *10 (Fed.Cl.Spec.Mstr. Sept. 22, 1997). In a decision on remand, explaining his prior decision that had been reversed by the Court of Federal Claims, the Special Master noted in dicta: "[M]y view has been that for a petitioner to make the necessary 'actual causation' showing, there must be a preponderance of all the evidence in the record indicating that the injury was vaccine-caused." *Id.*

Hodges, 9 F.3d at 961-62 ("The fact that the opinion of petitioner's doctors was rejected does not mean that the Special Master was demanding scientific certainty; he might simply have been demanding some degree of acceptable scientific support when concluding that the [petitioner's] claim for causation in-fact was not supported by a preponderance of the evidence."). This additional scientific support might come in the form of a medically accepted time frame between the vaccination and the onset of the subsequent condition. Or, if the petitioner has succeeded in presenting only evidence of biologic plausibility and a literal temporal proximity, the Special Master may look to other facts apparent in the record, including potential alternative causes, that may undermine the petitioner's case and lead the Special Master to conclude that the petitioner has failed to establish causation-in-fact. That a vaccine may cause a specific response or condition is not proof that it did in a particular case.[FN16] *Id.* at 961-62 & n. 4.

The court must emphasize that, ultimately, there appears to be no hard and fast rule for what specific, individual elements of proof a petitioner must present in order to establish a prima facie case of causation-in-fact; the rule is really one of reason, in which the Special Master gives greater weight to certain factors in certain cases depending on the facts of that particular case and the medical developments existing at that time. "Causation in fact under the Vaccine Act is thus based on the circumstances of the particular case, having no hard and fast per se scientific or medical rules." *Knudsen*, 35 F.3d

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FN16. This is not to say that biologic plausibility combined with literal temporal proximity will not ever satisfy the petitioner's burden of proof. The determination is one to be made by the fact finder in light of the entire record. Indeed, one can imagine a hypothetical case where a completely healthy individual receives a vaccine and suffers some condition shortly thereafter. The Special Master may conclude that, based on the entirety of facts-including the petitioner's relative health prior to the vaccine-the petitioner has satisfied his burden of proof. This might be the case if there is an absence of alternative causes apparent in the record or the biologic mechanism that petitioner demonstrates is particularly compelling.

at 548. Certainly, though, when a petitioner travels the plausibility route to causation-in-fact, he should endeavor to buttress his argument with more factors than just a plausible mechanism and a literal temporal relationship. In that analysis, the presence of a scientific temporal relationship and the elimination of alternative causes are persuasive factors that weigh significantly in the Special Master's evaluation.

C. Did The Special Master Employ The Proper Standard In Determining That Petitioners Failed To Prove Causation-In-Fact?

Employing this "rule of reason" regarding plausibility and causation-in-fact to the Special Master's decision in this case, it is clear that the decision withstands legal scrutiny. Arguing that the Special Master impermissibly heightened the legal standard in this case, petitioners claim that "[i]f the vaccine 'can cause' the injury via the process recognized, the fact that the process is shown to have occurred is prima facie proof that the 'timing' of the injury was a perfect fit for the theory of causation." Pet.'s Mem. of Objections at 29. This characterization, however, both oversimplifies the standard to which petitioners are held (as discussed above) and misstates what they seem to have actually proven.

First, it does not appear that petitioners ever succeeded in demonstrating that the mechanism of causation they espoused was, in fact, the biological process by which Richelle's condition developed. Had they been able to do so, then petitioners would have succeeded in proving direct causation and they would not have needed to rely on a circumstantial plausibility argument.

Instead, petitioners have demonstrated here that it is generally possible for the administration of certain vaccines to cause a reaction that, in certain genetically predisposed vaccinees, might trigger the manifestation of systemic onset JRA, or Still's disease. They have presented a medically accepted mechanism by which such a result might occur. Specific to Richelle, petitioners have demonstrated that she received a series of vaccines in March 1998, that she

experienced a typical temporary reaction to those vaccines, and that shortly thereafter she experienced the symptoms of a permanent condition (Still's disease). The record also presents evidence that shortly before Richelle received her March 1998 vaccines, she also experienced other temporary ailments that could have "triggered" the manifestation of her Still's disease according to the same mechanism that petitioners argue the vaccines operated. Petitioners did not offer any evidence that would establish a scientifically accepted or medically recognized time frame between a triggering event (such as the vaccine reactions or the tonsillitis or mycoplasma infection) and the manifestation of symptoms of Still's disease. And what is also significant, they did not offer evidence that tended to suggest that the vaccines were more likely to be the triggering event in Richelle's specific case than were her other ailments. In other words, other reasonably possible factors were not eliminated. In light of this entire record, taken as a whole, the court cannot conclude that it was error for the Special Master to decide that petitioners failed to establish by a preponderance of the evidence that the vaccines at issue were the but-for cause and substantial factor inducing injury. Rather, the Special Master was correct to hold that petitioners failed to establish a prima facie entitlement to compensation.

If the petitioners here had been able to demonstrate, as the Special Master indicated, that a temporal relationship in the medical sense existed-that is, that the onset of Richelle's Still's disease occurred upon the passage of a medically accepted period of time after her March 1998 vaccination and not after some other potential triggering event-then the weight of petitioner's circumstantial evidence would have been much stronger and this would be a much closer case. The presence of a medically recognized time frame between the trigger and the manifestation of symptoms, which would causally link the trigger and the condition, would serve here as a sufficient nexus to establish causation-in-fact, and would also have aided the court by eliminating alternative causes. Petitioners did succeed in demonstrating that Richelle

experienced vaccine-specific reactions within a six and fourteen day window that is typical of the five percent or so of the population that experiences such reactions. The Special Master noted these reactions were "typical" and "did not appear out of the ordinary." At no point, however, do petitioners appear to make the case for an accepted period of time between a "triggering" event and the onset of Still's disease symptoms, which in this case the Special Master determined to be about three weeks after Richelle's March 1998 vaccinations. Therefore, while the record appears clear that Richelle experienced a general reaction to the vaccines within a medically recognized time period, the same cannot be said with regard to the onset of her Still's disease symptoms, which the Special Master concluded to occur within a period distinct from her general vaccine reaction. Petitioners argue that the expression of Richelle's initial reaction to the vaccines was the beginning of a "logical sequence of cause and effect" that triggered a cascade of symptoms culminating with her Still's disease. They do not distinguish between Richelle's initial symptoms in early April 1998 (those the Special Master concluded were "typical post-vaccinal side effects") and her later symptoms weeks later that the Special Master deemed consistent with the Still's disease profile. They rely on evidence of an "entire chain of events from vaccination to autoimmune injury [that] occurred in the appropriate and expected time frame." Pet.'s Mem. of Objections at 28. The flaw in their argument that the Special Master seized on was that petitioners never established the expected time period in which the alleged "chain of events" would occur, but instead only established when the alleged "triggering event," or the initial vaccine reactions, would occur. There was no proof as to when any Still's-specific symptoms would be expected. The Special Master was not convinced that this was proof enough to establish causation-in-fact, especially in light of the fact that other contemporaneous events, each of which might have been potential triggers in petitioners' model, were present in the record. Had the petitioners demonstrated that Still's

disease symptoms would be expressed within one or two weeks of a triggering event, it would have supported petitioners'argument and made their case for causation-in-fact much stronger. On the other hand, if Still's disease symptoms generally manifest three to four weeks from a triggering event, for instance, then petitioners' model would seem to favor Richelle's tonsillitis or mycoplasma infection as a more likely triggering event. In light of these viable alternative causes of Richelle's Still's disease inherent in the record, the court can not conclude that the Special Master's rejection of the petitioner's causal argument was arbitrary or capricious. As noted above, the standard of proof that he employed in his analysis is consistent with the Vaccine Program case law, and his factual analysis considered relevant facts. The conclusion that he reached was rational.

D. Abuse Of Discretion

The petitioners also argue that the Special Master abused his discretion by raising the "critical time" issue sua sponte after hearing when neither party had themselves raised it as an issue during the case in chief. But this argument misses the mark because "[i]n general ··· the parties are responsible for the traditional tasks of identifying and developing information supporting or opposing an award, securing and presenting fact witnesses and expert testimony, and meeting their respective burdens of proof." Pet.'s Mem. of Objections at 6 (quoting Guidelines for Practice Under the National Vaccine Injury Compensation Program, § V, available at http://www.uscfc.uscourts.gov/OSM/OSMGuidelines.pdf). Here, the role of a medically accepted temporal relationship between a vaccination and the onset of a subsequent condition has long been recognized as an important, if not essential element of a petitioner's burden of proof in Vaccine Program cases. See *Hasler*, 718 F.2d at 205 ("[I]noculation is not the cause of every event that occurs within the ten day period [afterward]···· Without more, this proximate temporal relationship will not support a finding of causation."). It is recognized as one of the tools in a

petitioner's arsenal that may help to establish causation. See, e.g., *Stevens*, 2001 WL 387418 at *25-26. Indeed, establishing proof of a medically acceptable temporal relationship between the vaccination and the onset of the alleged injury was specifically identified by the Chief Special Master in *Stevens* as one of the essential criteria a petitioner needs to establish as part of his prima facie causation-in-fact case. *Id.* While the court does not wholly adopt the Chief Special Master's analytic framework set forth in *Stevens*,[FN17] but see *Althen*, 58 Fed.Cl. 270 (criticizing the analytic framework), that framework is key in this case because on several occasions the petitioners claim to have tried to prove their case based on the *Stevens* model.[FN18] Petitioners were therefore on notice of the unique role that the "critical time" element plays in Vaccine Program cases. Since the role of a medically acceptable temporal relationship is both a widely recognized issue in Vaccine Program cases, and since the petitioners here claim to have followed a framework that

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FN17. Here, Congress has provided no test by which the courts are to evaluate causation-in-fact claims. The courts, therefore, should be wary to blindly or mechanistically apply a court-made test as some sort of talisman that replaces the process of applying the law. See *Gasperini v. Center for Humanities, Inc.*, 518 U.S. 415, 465, 116 S.Ct. 2211, 135 L.Ed.2d 659 (1996) (citing *Hanna v. Plumer*, 380 U.S. 460, 466-67, 85 S.Ct. 1136, 14 L.Ed.2d 8 (1965)). On the other hand, analytic frameworks such as that espoused by the Chief Special Master in *Stevens* do play an important role as a starting point for analysis. As an element of a broader "rule of reason" that is more of a means than an end, such a framework can play an important jurisprudential role in the absence of a hard-and-fast rule set forth by Congress.

FN18. See Pet.'s Mem. of Objections at 4 n. 6 (quoting *Stevens* "Petitioners must satisfactorily prove that the onset occurred within a time frame deemed medically appropriate according to the scientific or medical evidence"), 12 (noting that the parties had been directed by the Special Master to address the *Stevens* analytic framework), 13 ("Beginning with the Prima Facie memo, Petitioners religiously followed the template of the *Stevens* and *Shyface* cases."), 13 n. 27 (noting that *Stevens* contemplates "proof of a medically acceptable temporal relationship between the vaccination and the onset of the injury").

explicitly includes that relationship as one of its key components, the court concludes that the Special Master did not err or abuse his discretion in raising this issue in his opinion, despite the fact that it may not have been specifically addressed at hearing or raised as an issue by respondent.

E. Alternative Causation

Finally, the petitioners challenge the Special Master's reliance on potential alternative causes of Richelle's Still's disease, which in his view weakened the petitioner's causation-in-fact case because they never discounted the role of these other causes in the context of the cytokine mechanism that petitioners espoused. Petitioners point to statute and case law [FN19] that seem to implicitly place upon the government the burden of proving the existence of alternate causation by a preponderance of the evidence. Essentially, they argue that the government never proved that a factor unrelated to the vaccine caused Richelle's Still's disease, so therefore the Special Master should not have considered the role of alternative causes vis-a-vis the vaccines in deciding this case.

In addition to either establishing an on-Table injury or proving causation-in-fact, the Vaccine Act requires the fact finder to determine that "there is not a preponderance of the evidence that the ··· injury ··· is due to factors unrelated to the administration of the vaccine." *Grant*, 956 F.2d at 1149-50 (quoting § 300aa-13(a)(1)(B)) (alterations in original). In other words, it must be demonstrated that there is an "absence of alternative causes" for the alleged injury. *Id.* "These are two separate inquiries under the statute···· [T]he Act requires a finding on both causation and alternative etiologies." *Id.* In an on-Table case where the petitioner has successfully demonstrated that he is entitled to the presumption of

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FN19. Petitioners cite to *Knudsen* and *Althen* to support their argument. The court notes that those two cases are inapposite to the present matter. *Knudsen* was an "on-Table" case; *Althen* was not a case in which potential alternative causes were at issue. See *Knudsen*, 35 F.3d 543; *Althen*, 58 Fed.Cl. 270.

causation, the burden of proof of alternative causation rests with the government. In other words, the government must affirmatively prove the presence of some alternative cause. See *Knudsen v. Sec'y of the Dep't of Health and Human Servs.*, 35 F.3d 543, 547 (Fed.Cir.1994) ("Thus, if a petitioner has ··· obtained the benefit of a presumption [by proving an on-Table condition], and the government cannot prove actual alternative causation for whatever reason, then the petitioner is entitled to compensation."). Particularly in on-Table cases, the role of § 300aa-13(a)(1)(B) is essential. Since petitioners obtain the presumption of causation merely by establishing that a Table injury occurred within an established temporal proximity to the vaccine, the statute provides a means by which respondent may overcome that presumption if, in fact, some factor unrelated to the vaccine caused the condition or illness.

Apportioning the burden of proof of alternative causation in off-Table cases where the petitioner attempts to establish causation-in-fact, however, has been the subject of considerable debate within this Circuit. Compare *Wagner v. Sec'y of the Dep't of Health and Human Servs.*, 37 Fed.Cl. 134 (1997) ("To the extent that the [Special Master's analysis] operated in this case to place the burden of disproving every alleged alternative cause on the petitioner ··· it is not in accordance with the requirements of the Vaccine Act.") with *Wagner v. Sec'y of the Dep't of Health and Human Servs.*, No. 90-2208V, 1997 WL 617035 (Fed.Cl.Spec.Mstr. Sept. 22, 1997) (on remand) ("[P]etitioner's theory [that the government bears the burden of proof of alternative causation in the first instance] leads to an interpretation of the 'actual causation' avenue of proof that is radically different from any that has been set forth in any published opinion during the Program's existence.") (dicta). Much of the apparent uncertainty on this issue seems to stem from the contrast between the legal standard of proof that the courts have employed as part of the traditional tort theory of actual causation and the statutory analysis required by § 300aa-13(a)(1)(B). See *Stevens*, 2001 WL 387418 at *21 & n. 58.

Despite potential ambiguities or other decisions from the Court of Federal Claims that may appear facially inconsistent, this court concludes that the overwhelming weight of authority in this Circuit is consistent with traditional notions of tort law that place an initial burden of proof regarding alternative causation on the petitioner-not as part of the § 300aa-13(a)(1)(B) "factor unrelated" test, but rather as part of establishing a prima facie case of causation-in-fact. Consistent with the Federal Circuit's instructions, discussed above, that an actual-causation vaccine petitioner "must prove by a preponderance of the evidence that the vaccine, and not some other agent, was the actual cause of the injury," *Munn*, 970 F.2d at 865 (emphasis added), the attendant burden of proof in an actual causation case subsumes the obligation to successfully eliminate potential alternative causes of the alleged injury that have been identified in the record. This is so because, in proving that the vaccine is the actual cause of the alleged harm, the petitioner bears the burden of proving that the vaccine was both the "but for" cause as well as a "substantial factor" of the harm. *Shyface*, 165 F.3d at 1351-52.

While this burden is separate and distinct from the § 300aa-13(a)(1)(B) "factor unrelated" examination that the fact finder must conduct once the petitioner has established causation, there may well be overlap in the types of facts that might be considered. See, e.g., *Johnson v. Sec'y of the Dep't of Health and Human Servs.*, 33 Fed.Cl. 712, 721 (Fed.Cl.1995) ("While petitioner is correct that, under the statute, § 300aa-13(a)(1)(B) is literally applicable in non-Table cases, logically, the application of that section fails to add anything to the required analysis."), aff'd 99 F.3d 1160 (Fed.Cir.1996) (table decision). This is not to say, however, that the § 300aa-13(a)(1)(B) "factors unrelated" analysis is formally "collapsed into a single determination," but see *id.*, because the Federal Circuit has made clear that they are "two separate inquiries," *Grant*, 956 F.2d at 1149-50, and because the statutory analysis only obtains once the petitioner has first made out a prima facie case of causation. See *Bradley v.*

Sec'y of the Dep't of Health and Human Servs., 991 F.2d 1570, 1575 (Fed.Cir.1993) ("[W]hen, as here, the special master concludes that a petitioner has not demonstrated by a preponderance of the evidence ··· causation required under subsection (A), the alternative causation theories of subsection (B) need not be addressed."). For practical purposes, though, the court's determination of whether the petitioner has proven causation in fact will necessarily incorporate an analysis of whether the petitioner has demonstrated that the vaccine is the substantial factor behind the injury, and this analysis requires recourse to and discounting of other potential factors behind the harm. See *Shyface*, 165 F.3d at 1351-52; see also *Johnson*, 99 F.3d 1160 (table decision) ("As a matter of logic, however, a preponderance of the evidence cannot show both actual causation by the vaccine and causation due to factors unrelated to the vaccine.") (citing *Bradley* and *Munn*).

"Thus, in a nontable case, the single inquiry is whether the petitioner has established by a preponderance of the record evidence that his or her injury or condition was actually caused by the vaccine." *Johnson*, 99 F.3d 1160. This does not suggest that the petitioner must discount every potential cause that exists within the entire realm of possibility, or "prove that an infinite number of potential causes were not at work causing the injuries suffered," *Wagner*, 37 Fed.Cl. at 139, but rather the petitioner must confront the range of potential causes that are evidenced in the record. See *Stevens*, 2001 WL 387418 at *26 ("Reasonable efforts to rule out known alternate causes is sufficient to meet the preponderance standard. The reasonableness of the efforts is usually apparent from the medical records.").

This conclusion is not inconsistent with other opinions from this court and its predecessor that implicitly place the burden of proof on the government in the § 300aa-13(a)(1)(B) "factors unrelated" analysis. See, e.g., *McClendon v. Sec'y of the Dep't of Health and Human Servs.*, 24 Cl.Ct. 329, 333 (1991). The *McClendon* court noted that:

If a prima facie case of entitlement exists, § 300aa-13(a)(1)(B)

instructs the fact finder to determine whether a preponderance of the evidence shows that the injury was due to 'factors unrelated' to the administration of the vaccine .... The Act implicitly places the onus of proving the existence of an alleged alternative cause squarely on the shoulders of the respondent.... [I]t is not the petitioners' burden to disprove all possible alternative causes in order to prevail.

Id. [FN20]This is a proper iteration of the allocation of the burden of proof once petitioner has established that he is entitled to the presumption of causation, either by demonstrating that his is an on-Table case or by proving causation-in-fact. Indeed, only once either of those preconditions to the presumption of entitlement are satisfied in accord with § 300aa-13(a)(1)(A) does the fact finder turn to subparagraph (B) to address the "factors unrelated" analysis. See *Bradley*, 991 F.2d at 1575. The element of analysis that is critical to this case, and seems to be either omitted or assumed away by other cases, is that in establishing his prima facie case of entitlement, the petitioner must discount other potential causal factors that the record reveals, because the required "substantial factor" analysis requires as much. This requirement does not saddle petitioner with the unfair burden of disproving the role of the entire spectrum of alternative causes or "every possible ground of causation," but rather limits the petitioner's burden to proving, by a preponderance of the evidence, why the vaccine at issue and not those other factors evidenced in the record was the substantial factor in the alleged injury. *Bunting v. Sec'y of the Dep't of Health and Human Servs.*, 931 F.2d 867, 873 (Fed.Cir.1991); see also *Wagner*, 37 Fed.Cl. at 139. If a

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FN20. The court notes that *McClendon* concluded that the petitioners had proven by a preponderance of the evidence the existence of a "table seizure disorder" and that the case was therefore an "on-Table" case. The petitioner was not obligated to prove causation-in-fact, but rather the presence of a Table injury. Once a Table injury had been established, therefore, the burden of proof for the § 300aa-13(a)(1)(B) analysis clearly, and properly, shifted to respondent. See *McClendon*, 24 Cl.Ct. at 336-37.

petitioner fails to satisfy this burden, then he has failed to establish his prima facie case of entitlement and the burden of proof for the § 300aa-13(a)(1)(B) inquiry never shifts to the respondent.

Therefore, in this case, the Special Master committed no error by factoring in to his analysis the unexplained role that causes other than the vaccines at issue may have played in triggering Richelle's Still's disease. These alternatives were present in the record and comprised part of the body of evidence that the Special Master was required to weigh in determining whether petitioners had succeeded in demonstrating, based on the record as a whole, that the vaccines at issue were indeed the but-for cause of the condition. Since the petitioners relied exclusively upon circumstantial evidence in proving their case, it was incumbent upon them to discount the role of these potential alternatives in order to prove that the vaccines were, more likely than not, the cause of Richelle's Still's disease. Without doing so, or without providing other persuasive evidence that tended to show that the vaccines specifically caused the disease, Richelle's other prior ailments remained as possible "triggers" that were just as likely as the vaccines to cause her Still's disease.

VI. Conclusion

For the foregoing reasons, the court AFFIRMS the Special Master's decision. The court, accordingly, dismisses the petition with prejudice.

IT IS SO ORDERED.

Appendix C

451 F.3d 1352

United States Court of Appeals,
Federal Circuit

Lisa Ann PAFFORD and Richard Leon Pafford, Parents and Next Friends of Richelle Lorrae Pafford , a minor, Petitioners-Appellants,
v.
SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent-Appellee.
No. 05-5106.
June 20, 2006.
Rehearing and Rehearing En Banc Oct. 24, 2006.

Robert T. Moxley, Gage and Moxley, of Cheyenne, Wyoming, argued for petitioners-appellants.
Melonie J. McCall, Trial Attorney, Torts Branch, Civil Division, United States Department of Justice, of Washington, DC, argued for respondent-appellee. With her on the brief were Peter D. Keisler, Assistant Attorney General and Timothy P. Garren, Director, and Vincent J. Matanoski, Assistant Director.

Before LOURIE, RADER, and DYK, Circuit Judges.

Dissenting opinion filed by Circuit Judge DYK.

RADER, Circuit Judge.
Richelle Pafford (Pafford) alleges that her DTaP, MMR and OPV vaccinations resulted in the onset of systemic Juvenile Rheumatoid Arthritis. [FN1] *Pafford v. Sec'y Of Health &*

FN1. DTaP stands for diphtheria, tetanus (commonly known as lockjaw), and pertussis (commonly known as whooping cough.) OPV stands for oral (continued...)

Human Servs., 2004 WL 1717359 (Ct.Fed.Cl.2004) (*Trial Court Decision*). Because the Special Master correctly interpreted and applied the relevant statutory test for proving causation in off-table cases, this court affirms.

I

On March 24, 1998, Pafford received a series of vaccinations from her doctor, Dr. Jay Schmidt (Dr. Schmidt). *Trial Court Decision*, 2004 WL 1717359, at *1. The vaccinations administered by Dr. Schmidt during this office visit included a DTaP vaccination, Pafford's fourth OPV vaccination, and a second MMR vaccination. *Id.* Pafford had received routine childhood immunizations prior to this. Both her first and second DTP, OPV, and Hib vaccinations were normal. [FN2] *Id.* However, she developed a faint maculopapular rash approximately seventeen days after receiving her third DTP and OPV vaccinations and her first MMR vaccination. *Id.* Earlier that month, on March 5, 1998, Dr. Schmidt had treated Pafford for a cold and diarrhea. Approximately one week later, on March 12, 1998, Pafford was seen by Dr. Schmidt for inflamed tonsils with white patches on them and a fever of 101-102 degrees Fahrenheit. *Id.* She tested negative for strep. *Id.* At her March 24, 1998 visit, Dr. Schmidt examined Pafford and noted that the tonsillitis had cleared. *Id.* As was the case throughout her early childhood years, Dr. Schmidt concluded that Pafford was showing normal growth and development without any unusual medical problems. *Id.* On April 4, 1998, Pafford developed a fever and complained of neck pain. *Id.* The fever resolved itself, but the neck pain continued. *Id.* Dr. Schmidt saw Pafford on April 7, 1998 for her neck pain. *Id.* By that time, she had developed a diffuse, pink, macular rash, whitish spots on her tongue. *Id.* She also complained of limb pain. *Id.* Dr. Schmidt diagnosed her with

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(...continued)
poliovirus vaccine.

FN2. DPT is an older version of the DTaP vaccination. Hib stands for Haemophilus Influenzae Type b vaccine.

a vaccine-induced rash and recommended that she avoid exposure to others for five days. *Id.* On April 13, 1998, Pafford was taken to a local hospital emergency room with a fever, vomiting, pain on being touched and a rash on her hands, legs, chest, and upper abdominal area. *Id.* at *2. The hospital doctor, Dr. Bell, noted that "[t]he rash was very viral in character and I did not feel it was related to her immunizations but suggested a CBC to see if it supported the viral picture." *Id.* Pafford was admitted and her symptoms quickly dissipated. *Id.* She tested positive for a bacterial infection known as "mycoplasma" which Dr. Bell determined to be the cause of Pafford's symptoms. *Id.* She was released from the hospital the next day because her rash and fever had disappeared. *Id.* On April 20, 1998, Dr. Bell saw Pafford for a recurrence of her symptoms. Dr. Bell diagnosed Pafford with systemic onset Juvenile Rheumatoid Arthritis, also known as Still's disease. *Id.*

Pafford's parents, on behalf of Pafford, brought a claim under the National Childhood Vaccine Injury Act, 42 U.S.C. §§ 300aa-1 to 34, in the Court of Federal Claims. They alleged that their daughter's development of Still's disease was a result of the vaccinations she received on March 24, 1998. *Id.* at *1. On July 16, 2004, Special Master Richard Abell issued a decision denying Pafford's claim. *Id.* Special Master Abell determined that a vaccine can cause Still's disease but that Pafford had not sufficiently demonstrated that in her case the vaccine did cause the development of Still's disease. *Id.*

Following an appeal, Court of Federal Claims Judge Lawrence J. Block issued an opinion sustaining the Special Master's decision. *Pafford v. HHS*, 64 Fed.Cl. 19 (2005). Pafford filed a motion for reconsideration alleging "legal error with regard to standards of proof and the allocation of burdens" which was denied on March 8, 2005.

II.

This court reviews the United States Court of Federal Claims' review of the Special Master's decision without deference. *Hines v. Sec'y of Health & Human Servs.*, 940 F.2d 1518, 1523-24 (Fed.Cir.1991). Thus, this court examines the Special

Master's legal determinations under a "not in accordance with law" standard and factual determinations under an "arbitrary and capricious" standard. *Munn v. Sec'y of Health & Human Servs.*, 970 F.2d 863, 870 n. 10 (Fed.Cir.1992).

Generally a petitioner can obtain compensation under the vaccine injury program in two ways. See *id.* at 865. In a "table" case, the petitioner has an initial burden to prove an injury listed in the Vaccine Injury Table within the prescribed time period under the requirements of 42 U.S.C. § 300aa-14(a). See *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1319 (Fed.Cir.2006) (citations omitted). Upon satisfying this initial burden, the petitioner earns a presumption of causation. At that point, the burden shifts to the respondent to prove that a factor unrelated to the vaccination actually caused the illness, disability, injury, or condition. 42 U.S.C. §§ 300aa-13(a)(1)(A),(B).

The other avenue for compensation does not involve the presumption of causation conferred by the table. In an "off-table" case (also known as a "causation-in-fact" claim), the petitioner cannot obtain a presumption of causation. Rather, the petitioner in an off-table case has the burden to prove the vaccination in question "caused" the illness, disability, injury, or condition. 42 U.S.C. §§ 300aa-13(a)(1), -11(c)(1)(C)(ii)(I). Pafford does not allege she suffered a table injury. Thus, Pafford must prove causation-in-fact or that the vaccine was actually the cause of her injuries.

Under this court's precedent, Pafford must prove by preponderant evidence both that her vaccinations were a substantial factor in causing the illness, disability, injury or condition and that the harm would not have occurred in the absence of the vaccination. *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352 (Fed.Cir.1999) ("We adopt the Restatement rule for purposes of determining vaccine injury, that an action is the 'legal cause' of harm if that action is a 'substantial factor' in bringing about the harm, and that the harm would not have occurred but for the action."). This court recently articulated an alternative three-part test. To show causation in fact, the petitioner must

show:

(1) a medical theory causally connecting the vaccination and the injury;

(2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) ··· a proximate temporal relationship between the vaccination and injury.

Capizzano, 440 F.3d at 1324 (citing *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed.Cir.2005)). Of course, as noted in *Shyface*, these prongs must cumulatively show that the vaccination was a "but-for" cause of the harm, rather than just an insubstantial contributor in, or one among several possible causes of, the harm.

The Special Master applied the tests of *Althen* and *Shyface* correctly in this case. Specifically, the Special Master indicated:

First, a petitioner must provide a reputable medical theory causally connecting the vaccination and the injury. In fine, can [the] vaccine(s) at issue cause the type of injury alleged? *Second*, a petitioner must also prove that the vaccine actually caused the alleged symptoms in her particular case.

Trial Court Decision, 2004 WL 1717359, at *4 (emphasis in original). The first prong of the Special Master's test is identical to the first prong of the *Althen* test. *Capizzano*, 440 F.3d at 1324 (citing *Althen*, 418 F.3d at 1278). The Special Master's inquiry also gave effect to the "logical sequence of cause and effect" at the heart of the second prong of the *Althen* test. *Trial Court Decision*, 2004 WL 1717359, at *6 (discussing Dr. Levin's testimony linking Pafford's March 1998 vaccinations to the onset of Still's disease). Most importantly, the second prong of the Special Master's test in this case restates correctly that the petitioner must show that the vaccine was the "but for" cause of the harm according to *Shyface*, or in other words, that the vaccine was the "reason for the injury" as stated in the second prong of the *Althen* test. Finally, the Special Master also required proof of a proximate temporal relationship between Pafford's vaccinations and the onset of Still's disease commensurate

with the third prong of the *Althen* test. *Trial Court Decision*, 2004 WL 1717359, at *9 ("The link missing from Petitioner's argument ··· was the lack of any defined time period in which one would expect to see the onset of Still's disease subsequent to a triggering event."). Thus, this court perceives no significant difference between the Special Master's test and that established by this court in *Althen* and *Shyface*.

III.

This court turns next to the evidence of record on causation-in-fact. Notably, the causation evidence of record consists primarily of testimony from two of Pafford's experts, Drs. Levin and Geier, and scientific literature on which their testimony was based. As discussed below, this court finds it was not arbitrary and capricious for the Special Master to conclude on this record that Pafford did not prove causation by preponderant evidence.

Applying the causation test to the facts before the court, the Special Master determined that Pafford proved only one of the two prongs of his test by preponderant evidence. Specifically, the Special Master noted, while "it is biologically plausible that one or more of the vaccinations at issue could cause the onset of Still's disease[,]" *Trial Court Decision*, 2004 WL 1717359, at *5, Pafford did not prove that the vaccinations were a but-for cause of her contracting Still's disease (i.e., Pafford failed to satisfy the "but-for" prong of the Shyface test), *id.* at *9. The Special Master was particularly troubled by the lack of evidence demonstrating "any defined time period in which one would expect to see the onset of Still's disease subsequent to a triggering event." *Id.*

To the Special Master, the absence of temporal linkage evidence prevented him from finding that a vaccination was the reason for the injury rather than other contemporaneous events unrelated to the vaccinations. *Id.* at *7 ("[A]bsent an appropriate time frame, the Court cannot find the mere temporal proximity of the vaccination and injury dispositive."). These contemporaneous events included: (1) a positive test for mycoplasma (a type of bacteria); (2) x-rays showing a thickening of the sinus membrane consistent with

a sinus infection; (3) an earlier bout of tonsillitis; and (4) an earlier cold accompanied by diarrhea. *Id.* at *8. Thus, according to the Special Master, Pafford did not prove by preponderant evidence that one or more of her vaccinations were a "but-for" cause of her contracting Still's disease.

On appeal, Pafford argues "[t]he special master placed an untoward and legally impermissible burden on petitioners" as part of the but-for inquiry to prove it was the vaccinations rather than the other contemporaneous events that triggered her Still's disease. Brief for Pafford at 54, *Pafford v. Sec'y of Health & Human Servs.*, No. 05-5106, 451 F.3d 1352, 2006 WL 1679714 (Fed.Cir.2006) (Petitioner's Brief); see *Trial Court Decision*, 2004 WL 1717359, at *4 ("Ruling out other potential causes is an essential element but does not itself establish causation."). Pafford argues that "[t]his is contrary to the express terms of the statute, whereby § 300aa-13 (a)(1)(B) contemplates the grant of compensation unless alternate causation by known factors is shown 'by a preponderance.'" Petitioner's Brief at 54 (emphasis in original). Pafford relies primarily on two of this court's cases, *Shyface* and *Grant* (as interpreted by *Shyface*) for the proposition that a petitioner need not rule out alternative causes in proving actual causation.

Contrary to Pafford's reading, *Shyface* and *Grant* do not stand for this premise. *Shyface* was a vaccine injury case involving an infant's April 1, 1993 DPT vaccination. [FN3] *Shyface v. Sec'y of Health & Human Servs.*, 1997 WL 829404, at *1 (Ct.Fed.Cl.1997), rev'd, 165 F.3d 1344 (Fed.Cir.1999). Four days after inoculation, the infant was taken to a hospital with a fever hovering between 109 and 110° F; tragically the infant died from the fever the same day. *Id.* at *2. Subsequent tests revealed the presence of a bacterial infection that could not be ruled out as the cause of death. *Id.* Thus, at trial, petitioners' expert theorized the DPT vaccination "caused" the

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FN3. DPT is an older version of the DTaP vaccination. This vaccination is given for the prevention of diphtheria, pertussis, and tetanus.

infant's fever, which was then significantly exacerbated by the infection. *Id.* at *5. In other words, petitioners' expert argued there were two "but-for" causes, the vaccination and the infection, each of the "but-for" causes being a substantial factor in the infant's death. When presented with this theory, the Special Master found preponderant evidence linking the DPT vaccination to the infant's death, but still rejected petitioners' claim because "it is impossible to know with any degree of confidence, which source is the predominant cause of death." *Id.* at *8.

On appeal, this court reversed. *Shyface*, 165 F.3d at 1353. This court held that, in order to establish a prima facie case, the petitioners had to show "that the DPT vaccine was both a but-for cause of and a substantial factor in [the infant's] death." *Id.* The court went on to explain that, while the vaccination must be a "substantial factor" in the infant's death, it need not be the sole factor or even the predominant factor. *Id.* at 1352-53. Thus, the court reversed the Special Master's decision in favor of respondent; the Special Master should have awarded compensation to the petitioners who had proven the DPT vaccine was both a but-for cause of and a substantial factor in the infant's death. *Id.* at 1353.

Unlike *Shyface*, the petitioner here never established that the vaccinations were a but-for cause of her contracting Still's disease. Thus, this case does not feature several "but-for" causes, one of which is a vaccination. Rather, the Special Master concluded he was unable to tell whether any of the vaccinations made any contribution to her contracting Still's disease due, in part, to the absence of "evidence indicating an appropriate time frame in which Still's disease will manifest subsequent to a triggering event." *Trial Court Decision*, 2004 WL 1717359, at *7. "Without such a defined time period, the link between the vaccinations and the injury is tenuous." *Id.* at *9. As noted earlier, this reasoning applies properly the tests of *Althen* and *Shyface*.

Evidence demonstrating petitioner's injury occurred within a medically acceptable time frame bolsters a link between the injury alleged and the vaccination at issue under the "but-for"

prong of the causation analysis. See *Capizzano*, 440 F.3d at 1326 (finding medical opinions that explain how a vaccine can cause the injury alleged coupled with evidence demonstrating a close temporal relationship "are quite probative" in proving actual causation). If, for example, symptoms normally first occur ten days after inoculation but petitioner's symptoms first occur several weeks after inoculation, then it is doubtful the vaccination is to blame. In contrast, if symptoms normally first occur ten days after inoculation and petitioner's symptoms do, in fact, occur within this period, then the likelihood increases that the vaccination is at least a factor. Strong temporal evidence is even more important in cases involving contemporaneous events other than the vaccination, because the presence of multiple potential causative agents makes it difficult to attribute "but-for" causation to the vaccination. After all, credible medical expertise may postulate that any of the other contemporaneous events may have been the sole cause of the injury. Thus, it was entirely proper for the Special Master to require Pafford to prove but-for causation, including some showing of temporal relationship between the vaccination(s) and the onset of injury.

Moreover, the Special Master's requirement for strong temporal evidence is consistent with the third prong of the Althen test: demonstrating a proximate temporal relationship between the vaccination and the injury. See *Althen*, 418 F.3d at 1278. Again, without some evidence of temporal linkage, the vaccination might receive blame for events that occur weeks, months, or years outside of the time in which scientific or epidemiological evidence would expect an onset of harm.

Turning to the evidence of record, neither of Pafford's two experts, Drs. Levin and Geier, provided sufficient evidence for the Special Master to conclude the onset of Still's disease occurred within the medically acceptable time frame. Dr. Levin explained that the DTaP, MMR and OPV vaccines can, in some individuals, trigger an autoimmune inflammatory

disorder that causes the release of cytokines, [FN4] which in turn cause the symptoms of Still's disease. *Trial Court Decision*, 2004 WL 1717359, at *5. Dr. Levin did not, however, provide any evidence about a medically acceptable time frame for the onset of the disease following the vaccination. Transcript of Record at 172-173, *Pafford v. Sec'y of Health & Human Servs.*, No. 01-165V, 2004 WL 1717359 (Ct.Fed.Cl.2004) (*Trial Transcripts)* (emphasis added). Dr. Levin also did not discuss in detail the other contemporaneous events unrelated to the vaccinations. Thus, the Special Master properly concluded, under our arbitrary and capricious standard of review, that Dr. Levin's testimony standing alone was not sufficient to prove the medically acceptable time frame or to link the onset of Still's disease to the vaccinations in this case.

In addition to Dr. Levin, Dr. Geier sought to provide testimony on this point. Specifically, Dr. Geier testified about the medically acceptable time frame for arthralgia episodes and joint syndromes generally. *Trial Transcripts* at 39-40; Petitioner's Brief at 10. The Special Master found Dr. Geier's testimony (and the scientific literature on which his testimony was based) insufficient for at least two reasons. In the first place, the Special Master noted correctly that evidence about the temporal relationship for arthralgia episodes and joint syndromes in general does not show the specific temporal relationship for Still's disease. *Trial Court Decision*, 2004 WL 1717359, at *7 n. 42. The Special Master also questioned Dr. Geier's qualifications because he is not certified in the areas of rheumatology, pathology, or immunology. *Id.* at *1 n. 2. Notably, this court accords great deference to a Special Master's determination on the probative value of evidence and the credibility of witnesses. See *Lampe v. Sec'y of Health & Human Servs.*, 219 F.3d 1357,

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FN4. Cytokine: "a generic term for non-antibody proteins released by one cell population on contact with a specific antigen, which act as intercellular mediators, as in the generation of an immune response." *Trial Court Decision*, 2004 WL 1717359, at *5 n. 29.

1360 (Fed.Cir.2000) (noting that the probative value of the evidence and the credibility of the witnesses are matters within the purview of the fact finder). On this record, the court cannot discern any reversible error in the Special Master's findings that Dr. Geier did not prove the temporal relationship between Still's disease and the vaccination.

Without credible testimony from either Dr. Geier or Dr. Levin on the medically acceptable time frame, the record contains little evidence linking Still's disease to the vaccinations in this particular case and leaves Pafford without adequate evidence to show "but-for" causation under this court's causation standards. See *Trial Court Decision* , 2004 WL 1717359, at *7 ("Petitioners provide no objective evidence indicating an appropriate time frame in which Still's disease will manifest subsequent to a triggering event."). Without a link between Still's disease and the vaccinations, the Special Master properly introduced the presence of the other unrelated contemporaneous events as just as likely to have been the triggering event as the vaccinations. *Id.* at *8. Hence, petitioner did not show it was more likely that the vaccinations were a but-for cause of and a substantial factor in her contracting Still's disease.

IV.

In her final argument, Pafford alleges the Special Master committed a Due Process violation by raising the medically accepted time frame issue sue sponte at the close of trial, without providing her a full and fair opportunity to present evidence on this issue. The record, however, shows that the petitioner knew of the medically accepted time frame issue well before the end of the trial and chose to rely on Dr. Geier to provide the required evidence. Response to Order to Show Cause & Motion for Inclusion in "Omnibus" Rubella Arthritis Cases at 1-2, *Pafford v. Sec'y of Health & Human Servs.*, No. 01-165V (Ct.Fed.Cl.2001) (asserting "the onset of Still's disease appears to fit within the bounds of biological plausibility and medically significant temporal relationship to vaccination" in view of literature associating the condition with rubella vaccine); Petitioner's Brief at 30 ("Petitioners'

had determined the[y] would rely on Dr. Geier to address ··· the 'time frame' element ····"). While Dr. Geier did not supply sufficient admissible evidence to satisfy this critical portion of the causation test, Pafford's admitted reliance on Dr. Geier in this regard impeaches her Due Process argument.

V.

In summary, the Special Master did not err in requiring specific evidence about a medically acceptable time frame linking the onset of Still's disease to the vaccinations at issue. In the absence of such evidence, the court cannot say the Special Master's finding that Pafford failed to prove causation by preponderant evidence was arbitrary and capricious. Thus, this court affirms.

COSTS

Each party shall bear its own costs.

AFFIRMED

DYK, Circuit Judge, dissenting.

The majority today holds that petitioners seeking compensation under the National Childhood Vaccine Injury Compensation Program (the "Vaccine Act") must establish, as essential elements of a prima facie showing of causation in off-Table cases, both (1) a "proximate temporal relationship between [the] vaccinations and the onset of [injury]," *Ante* at 1356; and (2) an absence of "alternative causes" of the injury. *Ante* at 1357. While there are some unfortunate dicta in our cases that might support the majority's approach, our earlier holdings and the statute itself are to the contrary. The majority's interpretation of the Vaccine Act approves the efforts of the Special Masters to impose unwarranted bright-line tests for causation under the statute. I respectfully dissent.

I

This case involves the five-prong test for causation in off-Table cases announced by the Chief Special Master in *Stevens v. Secretary of the Department of Health and Human Services*, No. 99-594V, 2001 WL 387418 (Ct.Cl.Spec.Mstr. Mar. 30, 2001). That test required petitioners to establish: (1) medical plausibility; (2) confirmation of medical plausibility

from the medical community and literature; (3) an injury recognized by the medical plausibility evidence and literature; (4) a medically-acceptable temporal relationship between the vaccination and the onset of the alleged injury; and (5) the elimination of other causes. *Id.* at *23-*26. We have already held that prongs (2) and (3) of this test are inconsistent with the statute. *Althen v. Sec'y of Health & Human Servs* ., 418 F.3d 1274, 1279-81 (Fed.Cir.2005). We have also held invalid a sixth Special-Master-created rule requiring petitioners, in order to demonstrate causation in fact in off-Table cases, to supply at least one of four types of evidence: "epidemiologic studies; rechallenge; presence of pathological markers or genetic predisposition; or general acceptance [of the causal relationship] in the scientific and medical communities ...." *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1323 (Fed.Cir.2006). This case for the first time presents the issue of the validity of prongs (4) and (5) of the *Stevens* test. The Special Master in this case rejected the petitioners' claim based on these two requirements. See *Pafford v. Sec'y of Health & Human Servs.*, No. 01-0165V, 2004 WL 1717359, at *7, *9 (Ct.Cl.Spec.Mstr. July 16, 2004).

II

Here, the petitioners put on substantial evidence of causation. Their expert, Dr. Levin, testified that it is generally accepted in the medical community that "the symptoms of Still's disease are caused by cytokine expression." Levin and the government's expert agreed that "vaccines induce cytokine production." See *id.* at *5. As to Richie Pafford's case, Levin stated that "immune activation caused by DPT vaccinations is in turn caused by the release of the very cytokines that are elevated in Still's disease," and that although "the medical field had yet to develop testing sophisticated enough to identify specific cytokines" in patients, "indirect tests performed [on Richie] ... correlate[d] with the clinical symptomatology." *Id.* at *6. Levin concluded that "the only factor that seems associated with the development of this disease process [in Richie Pafford] is the vaccination." *Id.* The government did not introduce evidence to establish causation

by any factor unrelated to the vaccinations. *Id.* at *8. Acknowledging that it was a close case, the Special Master "painstakingly looked for the feather in Petitioners' argument that would tip the scales" as to causation in fact, but concluded that "the lack of any defined time period in which one would expect to see the onset of Still's disease subsequent to a triggering event," and the petitioners' failure to rule out causation by other "contemporaneous events," required denial of compensation. See *id.* at *9. The majority holds that this was proper.

III

Prong (4) of the *Stevens* test requires evidence of "a medically acceptable temporal relationship between the vaccination and the onset of the alleged injury" which "is defined through peer-reviewed literature ...." *Stevens*, 2001 WL 387418, at *25. To meet this requirement, "petitioners must satisfactorily prove that the onset occurred within a time frame deemed medically appropriate according to the scientific or medical evidence ...." *Id.* The Chief Special Master relied on no decision from this court for the requirement, but rather on other Special Master decisions and reports issued by the National Academy of Sciences' Institute of Medicine ("IOM"). See *id.* at *25 n. 78, *26 & n. 79.

The majority states that "the Special Master also required proof of a proximate temporal relationship between Pafford's vaccinations and the onset of Still's disease commensurate with the third prong of the *Althen* test." *Ante*, at 1356. The majority relies on the statement in *Althen*, 418 F.3d at 1281, that the "medically acceptable temporal relationship" requirement "is merely a recitation of this court's well-established precedent." The well-established precedent to which *Althen* was referring was apparently *Lampe v. Secretary of Health and Human Services* , 219 F.3d 1357 (Fed.Cir.2000), *Shyface v. Secretary of Health & Human Services*, 165 F.3d 1344 (Fed.Cir.1999), *Hodges v. Secretary of Health & Human Services* , 9 F.3d 958 (Fed.Cir.1993), and *Grant v. Secretary of Health & Human Services* , 956 F.2d 1144, 1149 (Fed.Cir.1992). These cases were cited in the

Althen opinion.

In fact, the precedent cited in *Althen* merely stands for the proposition that the temporal relationship between vaccination and injury may be a pertinent factor to consider in determining causation. In *Lampe*, for example, we stated only that "[t]he passage of time between an event and the consequences that are alleged to flow from it is often significant," not that a medically significant time interval is required. 219 F.3d at 1366. And in *Hodges*, we did not suggest that evidence of a temporal relationship is required—we held only that where the petitioners failed to prove a Table injury, literal temporal proximity to vaccination and the absence of other possible causes, alone, were insufficient to establish causation in fact for an off-Table injury. See 9 F.3d at 960-61. In *Shyface*, we addressed the standard for proving causation in off-Table cases in great detail and never once suggested a "medically established temporal relationship" requirement. Instead, we held that the petitioner must prove "that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury." 165 F.3d at 1352. Nor did we suggest in *Shyface* that a temporal relationship is necessary to establish either the but-for or substantial factor elements of causation. See *id.* at 1352-53. Significantly, in *Grant*, we rejected a temporal requirement. There, the petitioner sought compensation for encephalopathy-induced infantile spasms that began 10 days after a Quadrigen vaccination. [FN1] *Grant*, 956 F.2d at 1146-47. Because the spasms occurred outside the Table time period (3 days, 42 U.S.C. § 300aa-14(a)), the petitioner was required to establish causation in fact. The Special Master nevertheless found causation, relying on "evidence that pertussis as part of the Quadrigen vaccine has a heightened potential to cause ··· exactly the symptoms that occurred to [the petitioner] ····" *Id.* at 1149. On appeal, we rejected the

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FN1. The Quadrigen vaccine combined diphtheria, pertussis, tetanus and polio vaccines in a single administration. *Grant*, 956 F.2d at 1145.

government's argument, based on epidemiological studies, that the "lack of statistical proof [of an association between DTP vaccine and infantile spasms 10 days later] .... is dispositive on the issue of causation." Br. of Secretary of Health & Human Servs., *Grant*, 956 F.2d 1144, at 15-17; see *Grant*, 956 F.2d at 1148. We concluded that "[t]hese epidemiological studies ... are not dispositive of the actual causation question in this case." *Grant*, 956 F.2d at 1149. We affirmed the award of compensation, observing that:

[T]he Chief Special Master did not rely on expert testimony based on temporal association and studies of less direct relevance. Instead, the Chief Special Master relied on a preponderance of relevant scientific and medical evidence about the particular nature of Quadrigen. This court discerns nothing arbitrary, capricious, or unlawful in that reliance. *Id.*

In rejecting a temporal requirement for off-Table cases, *Grant* was entirely consistent with the statute. Indeed, the "medically acceptable temporal relationship" requirement is plainly contrary to the Vaccine Act. As we have repeatedly recognized, the purpose of the Vaccine Injury Table was to afford petitioners a presumption of causation for particular types of injury for which there is a medically accepted temporal relationship with vaccination. [FN2] Every Table injury has an associated time period. See 42 U.S.C. § 300aa-14(a) (2000). Congress explained that scientific research might establish additional temporal relationships

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FN2. See, *e.g.*, *Hodges*, 9 F.3d at 961 ("Bring the case within the timetable and specifications of a Table Injury and the statute does the heavy lifting-causation is conclusively presumed."); *Grant*, 956 F.2d at 1147 ("The Vaccine Table, in effect, determines by law that the temporal association of certain injuries with the vaccination suffices to show causation."); *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1527-28 (Fed.Cir.1993) (quoting *Grant*, 956 F.2d at 1147). Notably, the Chief Special Master in *Stevens* relied on the Secretary's 1995 explanation of the measles, mumps, and rubella vaccine/encephalopathy Table timeframe as an example of a "medically accepted temporal relationship." See 2001 WL 387418, at *25 (citing 60 Fed.Reg. 7678, 7692).

which, if found, would result in amendments to the time periods specified in the table:

The Committee anticipates that the research on vaccine injury and vaccine safety now ongoing and mandated by this legislation will soon provide more definitive information about the incidence of vaccine injury and that, when such information is available, the Secretary or the Advisory Commission on Childhood Vaccines ··· may propose to revise the Table ···H.R. Rep. 99-908, at 18 (1986), as reprinted in 1986 U.S.C.C.A.N. 6344, 6359. Thus the Vaccine Act provides that the Secretary of Health and Human Services may by regulation "add to, or delete from, the list of injuries ··· or may change the time periods for the first symptom or manifestation of the onset ··· of any such injury ···" in the Table. 42 U.S.C. § 300aa-14(c)(3) (2000); see 42 U.S.C. § 300aa-14(c)(1).

In 1995, for example, [FN3] the Secretary changed the Table time interval between administration of pertussis vaccines and "anaphylaxis or anaphylactic shock" from 24 hours to 4 hours, explaining that "the pediatric literature is clear in stating that severe anaphylactic reactions occur immediately with antigen exposure and rarely show their first manifestation after 4 hours." 60 Fed.Reg. 7678, 7686 (Feb. 8, 1995). The Secretary also changed the Table time interval between administration of the measles, mumps, and rubella vaccine and the onset of encephalopathy from 15 days to "5 to 15 days," explaining that "[s]ince viral replication is required for a viral vaccine-associated encephalopathy, a window for the expected time of onset is appropriate ···· [and] the 1991 [National Vaccine Advisory Committee] Subcommittee felt there was strong support in the literature to narrow the timeframe as above." *Id.* at 7692.

However, scientific research on vaccine-related injuries remains incomplete; thus it is not always possible to identify

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FN3. The Table was also revised in 1997 and 2002, 62 Fed.Reg. 7685 (Feb. 20, 1997); 67 Fed.Reg. 48558 (July 25, 2002), and is codified at 42 C.F.R. § 100.3.

the "medically accepted temporal relationship." In a 2000 report on the progress of the Vaccine Act, Congress noted that "[o]f the 76 adverse events IOM reviewed [in 1991 and 1994] for a causal relationship [with vaccination], 50 (66 percent) had no or inadequate research." H.R. Rep. 106-997, at 5 (2000).

In recognition of the uncertain state of scientific knowledge, the statute provides what is known as an off-Table remedy, allowing recovery where the petitioner can establish that the injury "was caused by a vaccine" listed in the Table, even though the particular injury is not listed in the Table. 42 U.S.C. §§ 300aa-11 (c) (1) (C) (ii) (I) & (II) (2000). Another important purpose of allowing recovery for off-Table injuries was to allow a petitioner to make a claim for an injury listed in the Table where the injury was not manifested during the medically accepted time frame set forth in the Table. [FN4] The Vaccine Act specifically authorizes compensation for petitioners who "sustained ··· any illness, disability, injury, or condition set forth in the Vaccine Injury Table the first symptom or manifestation of the onset of ··· which did not occur within the time period set forth in the Table but which was caused by a vaccine referred to in subparagraph (A)." 42 U.S.C. § 300aa-11(c)(1)(C)(ii)(II) (2000) (emphasis added). Thus the statute clearly contemplates that causation in fact may be established in off-Table cases without showing the "medically accepted temporal relationship" listed in the Table. [FN5]

FN4. The Secretary, in reducing the pertussis vaccines/anaphylaxis Table time interval from 24 hours to 4 hours, noted that "[p]etitioners may receive compensation under the [Vaccine Act] if they prove their injury was caused by the vaccination, even if onset was after the 4 hours specified in the Table." 60 Fed.Reg. at 7678.

FN5. Congress made clear that it did "not intend ··· to suggest that variance from the Table should act as a presumption against the petitioner but rather only that such a petitioner is not to be deemed eligible for compensation without further showings of causation." H.R. Rep. 99-908, at

(continued...)

This purpose would be directly thwarted if proof of a medically accepted timeframe were required to show causation in off-Table cases. But that is exactly what the majority requires here. In this case, there was substantial evidence regarding the biological mechanism of causation, even though the experts did not identify a medically accepted temporal relationship. See *Pafford*, 2004 WL 1717359, at *5-*6. Under the majority's holding, any petitioner who fails to establish a medically accepted temporal relationship automatically lacks an essential element of their prima facie case for causation in fact. That holding is inconsistent with the clear provisions of the statute and our prior holdings interpreting it.

III

The Special Master here concluded that "[r]uling out other potential causes is an essential element" of the petitioner's case. *Pafford*, 2004 WL 1717359, at *4. The Court of Federal Claims, after reviewing our cases and the Chief Special Master's decision in *Stevens*, concluded that in off-Table cases, the "initial burden of proof regarding alternative causation [is] on the petitioner ··· as part of establishing a prima facie case of causation-in-fact." *Pafford v. Sec'y of Health & Human Servs.*, 64 Fed.Cl. 19, 35 (2005). [FN6] The

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(...continued)
15.

FN6. See also *Pafford*, 64 Fed.Cl. at 30 ("The Federal Circuit has instructed that an actual-causation vaccine petitioner 'must prove by a preponderance of the evidence that the vaccine, and not some other agent, was the actual case of the injury.' *Munn*, 970 F.2d at 863 (emphasis added). This would seem to engender the need for a petitioner to eliminate other possible causes of the condition (other than the vaccine) that exist in the record."); *id.* ("··· petitioner[ ] must eliminate other reasonably possible causes that exist in the record to meet its burden of establishing a prima facie case for causation-in-fact."); *id.* at 35 ("[T]he overwhelming weight of authority in this Circuit is consistent with traditional notions of tort law that place an initial burden of proof regarding alternative causation on the petitioner ··· as part of establishing a prima facie case of causation-in-fact."); *id.* at 36

(continued...)

majority, in sustaining the Special Master's *1365 decision here, appears to agree. As with the temporal relationship prong, there is at least a fragment of dictum supporting this view. See *Munn v. Sec'y of Health & Human Services*, 970 F.2d 863, 865 (Fed.Cir.1992) ("The claimant must prove by a preponderance of the evidence that the vaccine, and not some other agent, was the actual cause of the injury."). Since the dictum in *Munn*, however, we have unequivocally held that, under section 300aa-13(a)(1)(B), the government bears the burden of proof regarding causation by "factors unrelated" to vaccination.

Section 300aa-13(a)(1) of the Vaccine Act provides, in pertinent part:

Compensation shall be awarded under the Program to a petitioner if the special master or court finds on the record as a whole—

(A) that the petitioner has demonstrated by a preponderance of the evidence [a Table injury or causation in fact], and

(B) that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition.

42 U.S.C. § 300aa-13(a)(1) (2000) (emphasis added). As we have recognized, the plain language and structure of this provision establish that the petitioner's burden to make a prima facie showing of either presumptive or actual causation set out in section 300aa-13(a)(1)(A) does not include the burden of proof regarding "factors unrelated" to vaccination set out in section 300aa-13(a)(1)(B)-"[t]hese are two separate inquiries under the statute." *Grant*, 956 F.2d at 1149 ("The

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(...continued)

("[I]n establishing his prima facie case of entitlement. the petitioner must discount other potential causal factors that the record reveals, because the required 'substantial factor' analysis requires as much."); *id.* at 36 ("··· it was incumbent upon [the petitioners] to discount the role of these potential alternatives in order to prove that the vaccines were, more likely than not, the cause of Richelle's Still's disease.").

Vaccine Act expressly separates the inquiry for alternative etiologies from the inquiry for causation.").

We have repeatedly held that the separate burden of proof regarding "factors unrelated" to vaccination belongs to the government in both Table and off-Table cases. See, e.g., *Jay v. Sec'y of Health & Human Servs.*, 998 F.2d 979, 984 (Fed.Cir.1993) (section 300aa-13(a)(1)(B) requires a "statutorily separate inquiry ··· [as to] whether an alternative causation has been proved by [the government]." (emphasis added)). In *Knudsen v. Secretary of Health & Human Services*, 35 F.3d 543 (Fed.Cir.1994), a Table case, the petitioners argued that the government failed to satisfy its burden of proof for its argument that the injury was caused by a viral infection rather than the vaccine. In defining the government's burden under section 300aa-13(a)(1)(B), we held that "[t]he government was required not only to prove the existence of an infection (here viral), but also to prove by a preponderance of the evidence that the particular viral infection present in the child actually caused the table injury complained of." *Id.* at 549. And in *Shyface*, an off-Table case, we rejected the government's argument that the statute requires the petitioner to establish "'that the vaccine is more likely than any other factor to have been directly responsible for the injury,'" 165 F.3d at 1349, and concluded that compensation was warranted because the petitioners made a prima facie showing of causation and the government "failed to prove that factors unrelated to the vaccine were principally responsible ····" *Id.* at 1353.

Indeed the Second Restatement of Torts, which we held in *Shyface* to be controlling in off-Table cases, 165 F.3d at 1351-52, provides that the defendant bears the burden of proof on alternate causation. The Restatement describes the prima facie showing of causation in cases involving more than one possible cause: "[i]f two forces are actively operating, one because of the actor's negligence, the other not because of any misconduct on his part, and each of itself is sufficient to bring about harm to another, the actor's negligence may be found to be a substantial factor in bringing it about." Restatement

(Second) of Torts § 432(2) (1965). "[T]he burden of proof that the tortious conduct of the defendant has caused the harm to the plaintiff is upon the plaintiff." *Id.* § 433B(1). But in cases involving multiple causes, the Restatement places the burden on the defendant to prove either "the apportionment" of the harm among the causes, or that one of the causes other than the defendant's conduct actually caused the entirety of the harm to the plaintiff. *Id.* §§ 433B(2) & (3). Contrary to the majority's view, the same allocation of burdens is required under the Vaccine Act.

IV

In summary, the majority incorrectly holds that petitioners, in order to make a prima facie case in off-Table cases, must establish a "medically accepted temporal relationship" between vaccine and injury and eliminate other possible causes of the injury. In doing so, the majority perpetuates causation requirements imposed on vaccine petitioners by the Special Masters, whose "role is to assist the courts by judging the merits of individual claims on a case-by-case basis, not to craft a new legal standard to be used in causation-in-fact cases." *Althen*, 418 F.3d at 1281. This case should be remanded for adjudication under the correct legal standard.

Appendix D

NOTE: Pursuant to Fed. Cir. R. 47.6, this order is not citable as a precedent. It is a public order.

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

ORDER

A combined petition for panel rehearing and for rehearing en banc having been filed by the Appellant, and a response thereto having been invited by the court and filed by the Appellee, and the petition for rehearing and response, having been referred to the panel that heard the appeal, and thereafter the petition for rehearing en banc and response having been referred to the circuit judges who are in regular active service,

UPON CONSIDERATION THEREOF, it is

ORDERED that the petition for panel rehearing be, and the same hereby is, DENIED and it is further

ORDERED that the petition for rehearing en banc be, and the same hereby is, DENIED.

The mandate of the court will issue on October 31, 2006.

FOR THE COURT

s/_____

Jan Horbaly
Clerk

Dated: 10/24/2006

cc: Robert T. Moxley
Melonie J. McCall

(filing stamp, Oct. 24, 2006)

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(CFC - 01-VV-165)

Appendix E

CONSTITUTIONAL AND STATUTORY PROVISIONS

United States Constitution

Article II—the President
Section 2, Clause 2.

He shall have Power, by and with the Advice and Consent of the Senate, to make Treaties, provided two thirds of the Senators present concur; and he shall nominate, and by and with the Advice and Consent of the Senate, shall appoint Ambassadors, other public Ministers and Consuls, Judges of the supreme Court, and all other Officers of the United States, whose Appointments are not herein otherwise provided for, and which shall be established by Law: but the Congress may by Law vest the Appointment of such inferior Officers, as they think proper, in the President alone, in the Courts of Law, or in the Heads of Departments.

* * *

Amendment V

No person shall . . . be deprived of life, liberty, or property, without due process of law . . .

United States Code

42 U.S.C. § 300aa-1. Establishment

The Secretary shall establish in the Department of Health and Human Services a National Vaccine Program to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines. The Program shall be administered by a Director selected by the Secretary.

* * *

HISTORICAL AND STATUTORY NOTES

* * *

Separability of Provisions

Section 322 of Pub.L. 99-660, as amended by Pub.L. 101-239, Title VI, § 6602, Dec. 19, 1989, 103 Stat. 2293; Pub.L. 101-502, § 5(g)(1), Nov. 3, 1990, 104 Stat. 1288, provided that:

"(a) In general.--Except as provided in subsection (b), if any provision [of] part A or B of subtitle 2 of title XXI of the Public Health Service Act [subparts A and B of part 2 of this subchapter], as added by section 311(a) [this subchapter], or the application of such a provision to any person or circumstance is held invalid by reason of a violation of the Constitution, both such parts shall be considered invalid.

"(b) Special rule.--If any amendment made by section 6601 of the Omnibus Budget Reconciliation Act of 1989 to title XXI of the Public Health Service Act [section 6601 of Pub.L. 101-239, amending sections 300aa-10, 300aa-11, 300aa-12, 300aa-13, 300aa-14, 300aa-15, 300aa-16, 300aa-17, 300aa-21, 300aa-23, 300aa-26, and 300aa-27 of this title] or the application of such a provision to any person or circumstance is held invalid by reason of the Constitution, subsection (a) shall not apply and such title XXI of the Public Health Service Act without such amendment shall continue in effect."

* * *

42 U.S.C. § 300aa-11. Petitions for Compensation

(a) General rule.

(1) A proceeding for compensation under the Program for a vaccine-related injury or death shall be initiated by service upon the Secretary and the filing of a

petition containing the matter prescribed by subsection (c) with the United States Claims Court...

* * *

(c) Petition content. A petition for compensation under the Program for a vaccine-related injury or death shall contain—

(1) except as provided in paragraph (3), an affidavit, and supporting documentation, demonstrating that the person who suffered such injury or who died—

(A) received a vaccine set forth in the Vaccine injury Table or, if such person did not receive such a vaccine, contracted polio, directly or indirectly, from another person who received an oral polio vaccine,

* * *

(1) (C) (ii)

(I) sustained, or had significantly aggravated, any illness, disability, injury, or condition not set forth in the Vaccine Injury Table but which was caused by a vaccine referred to in subparagraph (A) . . .

* * *

42 U.S.C. § 300aa-12. Court Jurisdiction

(a) General rule. The United States Claims Court and the United States Claims Court special masters shall, in accordance with this section, have jurisdiction over proceedings to determine if a petitioner under section 2111 [42 USCS § 300aa-11] is entitled to compensation under the Program and the amount of such compensation. The United States Claims Court may issue and enforce such orders as the court deems necessary to assure the prompt payment of any

compensation awarded.

* * *

(c) United States Claims Court special masters

(1) There is established within the United States Claims Court an office of special masters which shall consist of not more than 8 special masters. The judges of the United States Claims Court shall appoint the special masters, 1 of whom, by designation of the judges of the United States Claims Court, shall serve as chief special master. The appointment and reappointment of the special masters shall be by the concurrence of a majority of the judges of the court.

(2) The chief special master and other special masters shall be subject to removal by the judges of the United States Court of Federal Claims for incompetency, misconduct, or neglect of duty or for physical or mental disability or for other good cause shown.

* * *

(d) Special Masters.

* * *

(3)(A) A special Master to whom a petition has been assigned shall issue a decision on such petition with respect to whether compensation is to be provided under the Program and the amount of such compensation. The decision of the special master shall--

(i) include findings of fact and conclusions of law, and

(ii) be issued as expeditiously as practicable but not later than 240 days, exclusive of suspended time under subparagraph (C), after the date the petition was filed.

The decision of the special master may be reviewed by the United States Claims Court in accordance with subsection (e).

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* * *

(e) Action by the United States Claims Court.

(1) Upon issuance of the special master's decision, the parties shall have 30 days to file with the clerk of the United States Claims Court a motion to have the court review the decision. If such a motion is filed, the other party shall file a response with the clerk of the United States Claims Court no later than 30 days after the filing of such a motion.

(2) Upon the filing of a motion under paragraph (1) with respect to a petition, the United States Court of Federal Claims shall have jurisdiction to undertake a review of the record of the proceedings and may thereafter--

(A) uphold the findings of fact and conclusions of law of the special master and sustain the special master's decision.

(B) set aside any findings of fact or conclusion of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law, or,

(C) remand the petition to the special master for further action in accordance with the court's direction.

The court shall complete its action on a petition within 120 days of the filing of a response under paragraph

(1) excluding any days the petition is before a special master as a result of a remand under subparagraph (C). The court may allow not more than 90 days for remands under subparagraph (C).

(3) In the absence of a motion under paragraph (1) respecting the special master's decision or if the United States Court of Federal Claims takes the action described in paragraph (2) (A) with respect to the special master's decision, the clerk of the United States Court of Federal Claims shall immediately enter judgment in accordance with the special master's decision.

(f) Appeals. The findings of fact and conclusions of law of the United States Claims Court on a petition shall be final determinations of the matters involved, except that the Secretary or any petitioner aggrieved by the findings or conclusions of the court may obtain review of the judgment of the court in the United States court of Appeals for the Federal Circuit upon petition filed within 60 days of the date of the judgment with such court of appeals, within 60 days of the date of entry of the United States Claims Court's Judgment with such court of appeals.

42 U.S.C. § 300aa-13. Determination of eligibility and compensation

(a) General rule. (1) Compensation shall be awarded under the Program to a petitioner if the special master or court finds or the record as a whole—

(A) that the petitioner has demonstrated by a preponderance of the evidence the matters required in the petition by section 2111(c)(1)[42 USCS § 300aa-11(c)(1)], and

(B) that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition.

The special master or court may not make such a finding based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion.

(2) For purposes of paragraph (1), the term "factors unrelated to the administration of the vaccine"—

(A) does not include any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness, or condition, and

(B) may, as documented by the petitioner's evidence or other material in the record, include infection, toxins, trauma (including birth trauma and related anoxia), or metabolic disturbances which have no known relation to the vaccine involved, but which in the particular case are shown to have been the agent or agents principally responsible for causing the petitioner's illness, disability, injury, condition, or death.

(b) Matters to be considered. (1) In determining whether to award compensation to a petitioner under the Program, the special master or court shall consider, in addition to all other relevant medical and scientific evidence contained in the record—

(A) any diagnosis, conclusion, medical

judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death, and

(B) the results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions.

Any such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the court. In evaluating the weight to be afforded to any such diagnosis, conclusion, judgment, test result, report, or summary, the special master or court shall consider the entire record and the course of the injury, disability, illness, or condition until the date of the judgment of the special master or court.

* * *

(c) "Record" defined. For purposes of this section, the term "record" means the record established by the special masters of the United States Claims Court in a proceeding on a petition filed under section 2111[42 USCS § 300aa-11].